Form Approved: OMB NO. 0910-0037; Expiration Date xx/xx/xxxx *(See PRA Statement on last page)*

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 Paper Submission of Form FDA 2541d (Food Process Filing for Low-Acid Retorted Method)"

FDA USE ONLY **Date Received by FDA:** _ _ / _ _ / _ _ _ _ *(MM/DD/YYYY)*

Food Canning Establishment (FCE) Number *(Enter number assigned by FDA)*	Submission Identifier (SID) *(YYYY-MM-DD/SSS)*
_____	20 _ _ - _ _ - _ _ / _ _ _

A. Product Information

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.

- ☐ Aquaculture Seafood (e.g., farming of aquatic organisms including fish, mollusks, crustaceans, etc.)
- ☐ Baby Food (infant/junior foods including infant formula)
- ☐ Bakery Products (canned brown bread, bakery glazes)

Beans, Corn, or Peas

- ☐ Beans or Peas - Dry or Mature Soaked ☐ Beans, Corn, Peas - Fresh Succulent

Berry/Citrus/Core Fruit

- ☐ Berry/Citrus/Core Fruit
- ☐ Berry/Citrus/Core Fruit as a Jam, Jelly, Preserve, Drink, Syrup, Topping

- ☐ Beverage Base ☐ Breakfast Foods (liquid form – ready-to-eat, such as porridge, gruel)
- ☐ Cheese (does not include soy cheese or imitation dairy)
- ☐ Cocoa ☐ Coffee/Teas (excluding herbal and botanical teas)
- ☐ Crustacean (e.g., crab, shrimp, lobster, etc.) ☐ Dairy (milk-based)
- ☐ Dietary Supplement and/or herbal and botanical teas
- ☐ Dressings/Condiments (e.g., salad dressing, chutney, salsa, pepper sauce, etc.)
- ☐ Engineered Seafood (e.g., shelf-stable imitation crab, surimi, etc.) ☐ Fishery (finfish)
- ☐ Fishery (other aquatic (e.g., alligator, cuttlefish, frog legs, squid, etc.)

Fruit as a Vegetable

- ☐ Fruit as a Vegetable (e.g., eggplant, pumpkin, etc.)
- ☐ Fruit as a Vegetable Juice or Drink (e.g., eggplant juice, pumpkin juice, etc.)

A.1 (Food Product Group) *(Continued)*

- ☐ Fungi (e.g., mushrooms, pleurotus, truffles, etc.)
- ☐ Gelatin, Pudding Filling for Pies, Pie Filling (liquid form ready-to-eat such as apple pie filling, etc.)
- ☐ Gravies/Sauces (spaghetti sauce, mushroom gravy)
- ☐ Imitation Dairy (includes soy-based products)

Imitation/Pit/Mixed/Subtropical Fruit

- ☐ Imitation/Pit/Mixed/Subtropical Fruit
- ☐ Imitation/Pit/Mixed/Subtropical Fruit as a Jam, Jelly, Preserve, Drink, Syrup, Topping

Leafy/Stem Vegetables

- ☐ Leafy/Stem Vegetable
- ☐ Leafy/Stem Vegetable as a Juice or Drink (e.g., spinach juice, etc.)

- ☐ Meal Replacement/Medical Foods (e.g., supplemental liquid nutrition, etc.)
- ☐ Meat Products (Exotic Meat (emu, elk, etc.)) ☐ Mixed Fishery (e.g., seafood salad, etc.)

Mixed Vegetables

- ☐ Mixed Vegetables (e.g., carrots and peas, etc.)
- ☐ Mixed Vegetables as a Juice or Drink (e.g., carrot and green bean juice, etc.)

- ☐ Multiple Food (one container with a separate compartment for each product item (e.g., lasagna dinner, chop suey dinner, etc.)
- ☐ Noodle/Pasta ☐ Nut Spread and Nut Topping ☐ Other Vegetables
- ☐ Pet Food (e.g., dog/cat food, etc.)
- ☐ Rice, Wheat, Oat or Grain (liquid form – ready-to-eat such as grits)

A.1 (Food Product Group) *(Continued)*

Root and Tuber Vegetables

- ☐ Root/Tuber Vegetables (e.g., carrots, leeks, potatoes, etc.)
- ☐ Root/Tuber Vegetables as a Juice or Drink (e.g., carrot juice, etc.)

☐ Shelled Egg ☐ Shellfish (e.g., clams, mussels, oysters, etc.) ☐ Soup

☐ Sweet Goods/Dessert (liquid form – ready-to-eat, such as pudding)

☐ Vegetable Protein Products (e.g., imitation meat analog)

Vine/Other Fruit

- ☐ Vine/Other Fruit
- ☐ Vine/Other Fruit as a Jam, Jelly, Preserve, Drink, Syrup, Topping

☐ Wine Cooler

☐ Other ***(Specify below)***

_____

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

_____

_____

_____

3. What is the form of the product? ***(Select all that are applicable)***

☐ Chunks (e.g., chunks, nuggets, etc.) ☐ Cut ☐ Diced ☐ Filet ☐ French cut

☐ Liquid (i.e., all liquid no solids) ☐ On the Cob ☐ Paste/Puree ☐ Pieces

☐ Round/Spheres ☐ Shredded/Julienne ☐ Sliced (e.g., slices, quarters, strips, etc.)

☐ Spears/Stalks ☐ Whole

☐ Other ***(Enter product form)***

_____

4. What is the packing medium? ***(Select all that are applicable)***

☐ Brine ☐ Cream/Sauce/Gravy ☐ Oil ☐ Solid (no packing medium)

☐ Syrup ☐ Water ☐ None

☐ Other ***(Enter packing medium)***

_____

Continue to Section B.

B. Governing Regulation *(Refer to the precursor questions in the instructions)*

☒ **Low-acid (21 CFR 108.35 and 21 CFR Part 113)**

Continue to Section C.

C. Container Type *(Select one)*

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

1. ☐ Aluminum/Tinplate/Steel Can

a) What is the shape of the container? ***(Select one)***

☐ Cylindrical ☐ Oval ☐ Rectangular

☐ Irregular ***(Attach a picture or schematic. Provide name or a brief description of attachment below.)***

_____

☐ Other ***(Attach a picture or schematic. Provide name or a brief description of attachment below.)***

_____

b) How many pieces are used to construct the container? ***(Select one or more choices, as applicable)***

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

ii. ☐ 3-pieces – Do you use perforated divider plates? ☐ Yes ☐ No

How is the side seam sealed? ***(Select one)***

☐ Cemented ☐ Welded

c) Is the container a low-profile container?

☐ Yes *(If yes, answer either question c.i or c.ii.)* ☐ No *(If no, continue to Section D.)*

i. ☐ Heat penetration test was conducted with nested containers. ***(Attach study and picture or diagram. Provide name or a brief description of attachment below.)***

_____

ii. ☐ Nesting of containers prevented by: ***(Select one)***

☐ Brick Stacked ☐ Lid to Lid/Bottom to Bottom ☐ Perforated Divider Plates

☐ Racks ☐ Spiral

2. ☐ Ceramic/Glass

a) What is the shape of the container? ***(Select one)***

☐ Cylindrical ☐ Rectangular

☐ Irregular ***(Attach a picture or schematic. Provide name or a brief description of attachment below.)***

_____

☐ Other ***(Attach a picture or schematic. Provide name or a brief description of attachment below.)***

_____

b) Do you use perforated divider plates? ☐ Yes ☐ No

(Continue next page – Glass/Ceramic)

C. Container Type: 2. Ceramic/Glass *(Continued)*

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

☐ Yes *(Continue to c.i)* ☐ No *(Continue to c.ii-c.iv)*

i. What is the total overpressure used during processing? _ _._
(enter in pounds per square inch gauge (psig)) *(Continue to Section D)*

ii. What is the percent (%) headspace? _ _._

iii. What is the minimum initial temperature? _ _ _._ (enter in Fahrenheit)

iv. What is the vacuum? _ _._ (enter in inches of mercury (Hg))

3. ☐ Flexible Pouch

a) What is the shape of the container? ***(Select one)***

☐ Flat pouch ☐ Gable top ☐ Gable top/side gusseted ☐ Gusseted

☐ Irregular ***(Attach a picture or schematic. Provide name or a brief description of attachment below.)***

☐ Other ***(Attach a picture or schematic. Provide name or a brief description of attachment below.)***

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

☐ Yes *(Continue to b.i)* ☐ No *(Continue to c)*

i. ☐ Racks

☐ Other ***(Attach a picture. Provide name or a brief description of attachment below.)***

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

☐ Yes *(Continue to c.i)* ☐ No *(Continue to d)*

i. What is the total overpressure used during processing? _ _._ (enter in pounds per square inch gauge (psig))

d) What is the maximum thickness during retort processing? _ _ ._ _ (enter in inches)

e) What is the maximum residual air? _ _ _ (enter in cubic centimeters) ☐ Not Applicable

4. ☐ Retortable Paperboard Carton

a) What is the shape of the container? ***(Select one)*** ☐ Rectangular

☐ Other ***(Attach a picture or schematic. Provide name or a brief description of attachment below.)***

C. Container Type: 4. Retortable Paperboard Carton *(Continued)*

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

☐ Yes *(Continue to b.i)* ☐ No *(Continue to c)*

i. ☐ Racks

☐ Other ***(Attach a picture. Provide name or a brief description of attachment below.)***

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

☐ Yes *(Continue to c.i)* ☐ No *(Continue to d)*

i. What is the total overpressure used during processing? _ _._ (enter in pounds per square inch gauge (psig))

d) What is the maximum thickness during retort processing? _ _ ._ _ (enter in inches)

e) What is the maximum residual air? _ _ _ (enter in cubic centimeters) ☐ Not Applicable

5. ☐ Semi-Rigid

a) What is the shape of the container? ***(Select one)***

☐ Bowl ☐ Cylindrical ☐ Oval ☐ Rectangular ☐ Tray

☐ Irregular ***(Attach a picture or schematic. Provide name or a brief description of attachment below.)***

☐ Other ***(Attach a picture or schematic. Provide name or a brief description of attachment below.)***

b) Is this a compartmentalized container? ***(Select one)***

☐ Yes How many compartments? _ _ ☐ No

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

☐ HDPE (high-density polyethylene) ☐ HDPP (high-density polypropylene)

☐ Paperboard ☐ PET (polyethylene teraphthalate)

☐ Other ***(Enter material)***

(Continue next page – Semi Rigid)

C. Container Type: 5. Semi Rigid *(Continued)*

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

☐ Aluminum/Steel ☐ HDPE (high-density polyethylene)

☐ HDPP (high-density polypropylene) ☐ Nylon

☐ PET (polyethylene teraphthalate)

☐ Not Applicable

☐ Other ***(Enter material)***

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

☐ Double Seam ☐ Heat Seal ☐ Induction Weld ☐ Press Twist

☐ Snap On ☐ Threaded Closure ☐ Ultrasonic Seal

☐ Not Applicable

☐ Other ***(Enter seal type)***

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

☐ Yes *(Continue to f.i)* ☐ No *(Continue to g)*

i. ☐ Racks

☐ Other ***(Attach a picture. Provide name or a brief description of attachment below.)***

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

☐ Yes *(Continue to g.i)* ☐ No *(Continue to h)*

i. What is the total overpressure used during processing? _ _.__ (enter in pounds per square inch gauge (psig))

h) What is the maximum thickness during retort processing? _ _ .__ (enter in inches)

i) What is the maximum residual air? _ _ _ (enter in cubic centimeters) ☐ Not Applicable

6. ☐ Other ***(Enter container type)***

a) Attach schematic or picture of container. ***(Provide name or a brief description of attachment below.)***

C. Container Type: 6. Other *(Continued)*

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 of the container. If the container does not have a lid, specify Not Applicable.

Continue to Section D.

D. Container Size

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

1. Dimensions:

a) _ _ _ _ Diameter _ _ _ _ Height ***(Use for cylindrical shapes)*** (see accompanying instructions for proper coding)

b) _ _ _ _ Length _ _ _ _ Width _ _ _ _ Height/Thickness ***(Use for container shapes other than cylindrical)*** (see accompanying instructions for proper coding)

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

Continue to Section E.

E. Processing Method: Thermally Processed Non-Aseptic System

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

2. Heating Medium ***(Select one)***

a) ☐ High pressure assisted ☐ Microwave ☐ Ohmic (electrodes) ☐ Steam

☐ Steam-air ***(Attach a heat distribution study. Provide name or a brief description of attachment below.)***

☐ Water cascade ☐ Water immersion ☐ Water spray

☐ Other ***(Enter heating medium)***

Continue to Section F.

F. Process Mode

1. Mode (Select One). Only 1 Process Mode, either Agitating or Still, should be selected.

a) Agitating ***(Select one)***

i. ☐ Axial ***(Select one)***
☐ Batch ☐ Continuous

ii. ☐ End over End (Only batch)

iii. ☐ Oscillation (Only batch) ***(Select one)***
☐ High frequency ☐ Low frequency

b) Still ***(Select one)***

i. ☐ Horizontal

ii. ☐ Vertical

2. Cooker: What type of cooker do you use? ***(Select one)***

a) ☐ Crateless: Bottom Surface ***(Select one)***
☐ Solid ☐ Perforated

b) ☐ Hydrolock

c) ☐ Hydrostatic

d) ☐ Retort

e) ☐ Rotomatic/Rotary

f) ☐ Sterilmatic

g) ☐ Other ***(Enter cooker type)***

(For Other cooker type choice, attach documentation. Provide name or a brief description of attachment below.)

Continue to Section G.

G. Process System Critical Factors

1. What is the filling method(s) used to fill the product into the container? ***(Select all that apply)***
☐ Hand filling ☐ Piston filling ☐ Pocket filler
☐ Vibrating/Tumble filling ☐ Volumetric filling

2. How many phases are used to fill the container with the product? ***(Select one)***
☐ Single Phase ☐ Two Phase ☐ Three Phase *(Continue to a)*

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

G. Process System Critical Factors *(Continued)*

3. Is the product vacuum packed? ☐ Yes ☐ No

4. ☐ What is the container position in retort? ***(Select one) (Under Section F.1 when Agitating is selected, skip this question.)***
☐ Brick Stacked ☐ Horizontal ☐ Jumbled/Random
☐ Lid Down ☐ Lid Up ☐ Vertical

When heating medium of high pressure assisted, microwave, ohmic, or steam is selected in Section E, skip G.5 and G.6.

5. ☐ Minimum Come-Up-Time: _ _._ (enter in minutes) ***(Attach a temperature distribution study. Provide name or a brief description of attachment below.)***

When heating medium of steam-air is selected in Section E, skip G.6

6. ☐ Minimum Water Flow Rate: _ _ _ _ _._ (enter using gallons per minute (gpm))
☐ Not Applicable ***(Attach an explanation. Provide name or a brief description of attachment below.)***

Continue to Section H.

H. Product Critical Factors: *(Complete all product critical factor questions as delineated by process authority to assure commercial sterility.)*

1. Does the product contain particulates? ☐ Yes *(Continue to a)* ☐ No *(Continue to H.2)*

a) Is controlling the particulate size a critical factor?
☐ Yes *(Continue to b-d)* ☐ No *(Continue to H.2)*

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

c) Does your product contain fines? ☐ Yes *(Continue to c.i)* ☐ No *(Continue to d)*

i. ☐ What is the maximum percent? _ _ _._

d) Is full rehydration of the particulate a critical factor? ☐ Yes ☐ No

2. Does the product contain any dry ingredients?
☐ Yes *(Continue to a)* ☐ No *(Continue to H.3)*

a) What is the minimum % moisture of the hydrated dry ingredients before processing? _ _._ _
☐ Not Applicable

H. Product Critical Factors *(Continued)*

3. How are pieces arranged in the container? ***(Select one)***

☐ Head to Tail ☐ Heads/Tips Down ☐ Heads/Tips Up ☐ Horizontal
☐ Layered ☐ Vertical
☐ Not Applicable
☐ Other ***(Enter arrangement of pieces)***

For Other arrangement of pieces choice, attach documentation. Provide name or a brief description of attachment below.)

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

☐ Yes *(Continue to a)* ☐ No *(Continue to H.5)*

a) What is the % total solids? _ _._ _

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 *(Continue to a-c)* ☐ No *(Continue to H.7)*

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

b) What is the temperature when you measure the consistency/viscosity? (enter in Fahrenheit) _ _ _._

c) What is the consistency/viscosity? _ _ _._ _ _

What is the unit of measure? ***(Select one)***

☐ Centipoise
☐ Other ***(Enter units of measure)***

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

☐ Yes *(Continue to a-b)* ☐ No *(Continue to H.8)*

a) What is the maximum % starch added? _ _._ _

b) What type of starch is added?

H. Product Critical Factors *(Continued)*

8. Are other binders added? ☐ Yes *(Continue to a-b)* ☐ No *(Continue to H.9)*

a) What is the maximum % binder added? _ _._ _

b) What is the type of binder added?

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

☐ Yes *(Continue to a)* ☐ No *(Continue to Section I)*

a) What is the brix measurement? _ _._

Continue to Section I.

I. Process Source *(Complete the questions below)*

****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.***

1. Process Source

a) What is the Process Source?

(Attach support documentation. Provide name or a brief description of attachment below.)

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

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

☐ *Unknown/Locally Made ***(Attach pictures and documentation. Provide name or a brief description of attachment below.)***

Continue to Section J.

J. Scheduled Process: (Do *not* write in shaded areas -- Check appropriate box under column heading, when applicable, and enter numerical values on dashed lines.)

In the section below, please do NOT enter decimal points. They are already on the form. No blank spaces are allowed, therefore, enter leading zeros, where necessary.

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 Temp.	Process Time	Process Temp.	Fo (F18/250)	Thruput (Containers per Minute)	Headspace	a. Reel Speed	b. Reel Diameter	c. Steps per Turn of Reel	d. Chain/ Conveyer Speed	e. Cooker Capacity	f. Frequency Strokes per Minute	Maximum Fill Weight	Minimum Free Liq. at Closing	Minimum Container Closing Machine Gauge Vacuum	Other
							☐ Net ☐ Gross ☐ NA				☐ Feet ☐ Carriers ☐ Flights (per minute)			☐ NA		Temp. (+/- 3° F) _ _ _._	
Number	Number	°Fahrenheit	Minutes	°Fahrenheit	Minutes	Number	Inches	RPM	Inches	Number	Number	Number	Number	Ounces	Ounces	In. Hg.	
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K. Additional Information (Optional)

☐ Heat Penetration Data (optional) **:**

Enter applicable values: 1. j value _ _._ _ 2. fh value _ _ _._ _ 3. f2 value _ _ _._ _ 4. jc value _ _._ _ 5. fc value _ _ _._ _ 6. x (X_{bh}) value _ _ _._ _

☐ Heat Penetration Study ***(Attach document. Provide name or a brief description of attachment below.)***

_____

☐ Temperature Distribution Study ***(Attach document. Provide name or a brief description of attachment below.)***

_____

☐ Other ***(Attach document. Provide name or a brief description of attachment below.)***

_____

Comments:

Note: Under the terms and provisions of Title 18, Section 1001, United States Code, in any matter within the jurisdiction of the executive branch of the Government of the United States it is a criminal offense to falsify, conceal, or cover up a material fact; make any materially false, fictitious, or fraudulent statement or representation; or make or use any false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry.

If your process filing appears to be fabricated, the product on this form will not be in compliance with 21 CFR 108.35(c)(2). A process filing appears fabricated when it contains parameters that cannot be reconciled with one another, such that the filing does not describe a process that could actually be carried out. If we determine that your process filing appears fabricated, we will delete the filing from our system and notify you. We will not consider you to have complied with 21 CFR 108.35(c)(2) until you submit a completed process filing that does not appear to be fabricated.

Full Name (Please Type or Print)		Signature		
Establishment Name	State or Province	Country (other than U.S.)	Date	Telephone No.

LACF Contact Information

For more information, contact the LACF Registration Coordinator by e-mail at LACF@FDA.HHS.GOV or phone: 240-402-2411.

For paper submissions, send completed forms to:

Food and Drug Administration
LACF Registration Coordinator (HFS-303)
Center for Food Safety and Applied Nutrition
5001 Campus Drive
College Park, MD 20740-3835

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The time required to complete this collection of information is estimated to average 20 minutes per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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