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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)"

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

Food Canning Establishment (FCE) Number: _ _ _ _ _ _
Submission Identifier (SID) 20_ _-_ _-_ _/_ _ _ (YYYY-MM-DD/SSS)

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 (Select one):** ☐ Beans or Peas - Dry or Mature Soaked; ☐ Beans, Corn, Peas - Fresh Succulent;

Berry/Citrus/Core Fruit (Select one): ☐ 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 (Select one): ☐ Fruit as a Vegetable (e.g., eggplant, pumpkin, etc.) ☐ Fruit as a Vegetable Juice or Drink (e.g., eggplant juice, pumpkin juice, etc.);

☐ 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 (Select one):** ☐ Imitation/Pit/Mixed/Subtropical Fruit; ☐ Imitation/Pit/Mixed/Subtropical Fruit as a Jam, Jelly, Preserve, Drink, Syrup, Topping;

Leafy/Stem Vegetables (Select one): ☐ 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 (Select one): ☐ 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);

Root and Tuber Vegetables (Select one): ☐ 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 (Select one):** ☐ Vine/Other Fruit; ☐ Vine/Other Fruit as a Jam, Jelly, Preserve, Drink, Syrup, Topping; ☐ Wine Cooler;

☐ Other

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

3. What is the form of the product? ☐ Chunks (e.g., chunks, nuggets, etc.) ☐ Cut ☐ Diced ☐ Fillet ☐ 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? ☐ Brine ☐ Cream/Sauce/Gravy ☐ Oil ☐ Solid (no packing medium) ☐ Syrup ☐ Water ☐ None (i.e., the product is all liquid)
☐ 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 ☐ Irregular (**Attach a picture or schematic)** _____ ☐ Oval
   ☐ Rectangular ☐ Other **(Attach a picture or schematic)** _____
   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)** _____
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 ☐ Irregular **(Attach a picture or schematic)** _____ _____☐ Rectangular
☐ Other **(Attach a picture or schematic)** _____
b) Do you use perforated divider plates? ☐ Yes ☐ No
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)**_____
☐ Other **(Attach a picture or schematic)** _____
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)** _____

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)** _____
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)** _____

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 ☐ Irregular **(Attach a picture or schematic)** _____☐ Oval
☐ Rectangular ☐ Tray ☐ Other **(Attach a picture or schematic)** _____
b) Is this a compartmentalized container? ☐ 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) _____
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)
☐ Other (Enter material) _____ _____ ☐ Not Applicable

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 ☐ Other (Enter seal type) _____
☐ Not Applicable

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)** _____

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._____
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)** _____
☐ Water cascade ☐ Water immersion ☐ Water spray ☐ Other (Enter heating medium) _____

Continue to Section F.

F. Process Mode: (Select one)

1. Mode

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) _____ **(Attach documentation)** _____

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:_ _ _._ _

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)** _____

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)** _____

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 dry ingredients before processing? _ _._ _ ☐ Not Applicable

3. How are pieces arranged in the container? **(Select one)** ☐ Head to Tail ☐ Heads/Tips Down ☐ Heads/Tips Up ☐ Horizontal ☐ Layered ☐ Vertical
   ☐ Other (Enter arrangement of pieces) _____ **(Attach an explanation)** _____
   ☐ Not Applicable

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? _____

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

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2. What is the Manufacturer's Name and the Sterilizer Model: ____
   ☐ * Unknown/Locally Made **(Attach pictures and documentation)** ____

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.)

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) Agitating-Axial Continuous ONLY	Headspace	a. Reel Speed Agitating - End Over End or Agitating – Axial ONLY	b. Reel Diameter Sterilmatic Cooker ONLY	c. Steps per Turn of Reel Agitating-Axial Continuous ONLY	d. Chain / Conveyer Speed Hydrolock or Hydrostatic ONLY	e. Cooker Capacity Sterilmatic Cooker ONLY	f. Frequency Strokes per Minute Oscillation Agitating ONLY	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)** ____

☐ Temperature Distribution Study **(Attach document)** ____

☐ Other **(Attach document)** _____

Comments:

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
5100 Paint Branch Parkway
College Park, MD 20740-3835

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