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 Aseptic Systems (Form FDA 2541g)

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 2541g (Food Process Filing for Low-Acid Aseptic Systems)"

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.

- ☐ Baby Food (infant/junior foods including infant formula)
- ☐ Bakery Products (canned brown bread, bakery glazes)
- ☐ 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) ☐ Dairy (milk-based)
- ☐ Dietary Supplement and/or herbal and botanical teas
- ☐ Dressings/Condiments (e.g., salad dressing, chutney, salsa, pepper sauce, 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.)

- ☐ 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 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.)

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

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.)

- ☐ Nut Spread and Nut Topping ☐ Other Vegetables
- ☐ Rice, Wheat, Oat or Grain (liquid form – ready-to-eat such as grits)

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.)

- ☐ Soup ☐ Sweet Goods/Dessert (liquid form – ready-to-eat, such as pudding)
- ☐ Vine/Other Fruit as a Jam, Jelly, Preserve, Drink, Syrup, Topping
- ☐ Wine Cooler
- ☐ Other ***(Specify below)***

_____

2. Enter Product Name (e.g., Cheese Sauce (with Jalapeno Pieces), Pudding (Vanilla or Strawberry), etc.).

_____
_____
_____

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

- ☐ Liquid (i.e., all liquid no solids) ☐ Liquid with Solids (e.g., diced, chunks, pieces, etc.)
- ☐ Paste/Puree
- ☐ Other ***(Enter product form)***

_____

A. Product Information *(Continued)*

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

☐ Brine ☐ Cream/Sauce/Gravy ☐ Oil ☐ 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

ii. ☐ 3-pieces

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

☐ Cemented ☐ Welded

C. Container Type *(Continued)*

2. ☐ 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.)***

3. ☐ 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 single piece container?

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

c) Is this a compartmentalized container?

☐ Yes How many compartments? _ _ ☐ No

d) 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)***

Note: If "Yes" is selected as a single piece container in question 3.b, continue to Section D.

C. Container Type: 3. Semi-Rigid *(Continued)*

e) 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)***

f) 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)***

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

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

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 predominant material used to make the lid. 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, volume is acceptable for container size in lieu of container dimensions if package sterilizer does not depend on the container dimensions. Section D.3 (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 retangular shapes, pouches, or irregular shapes)*** (see accompanying instructions for proper coding)

2. Volume: _ _ _._ ***(Select one)***

- ☐ Fluid Ounces
- ☐ Gallons
- ☐ Liters
- ☐ Milliliters

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

Continue to Section E.

E. Product Processing Method: Thermally Processed using Aseptic Systems

Product Sterilization

a) What is the finished equilibrium pH of the product after processing? _ _._ _

b) Heating Method

i. ***(Select one)*** ☐ Direct Heating ☐ Indirect Heating

ii. What is the Thermal Expansion Coefficient? _._ _

iii. Where is the product flow rate controlled? ***(Select one)***

☐ Before the heater *(Continue to b.iii.1)* ☐ After the heater *(Continue to c)*

(1) Volume Expansion Factor: _._ _ (Direct Heating Only)

c) What is the Manufacturer's name and the model number of the Product Sterilization System?

d) What is the Process Source of the Product Sterilization System?

(Attach Process Source Document. Provide name or a brief description of attachment below.)

e) What is the date of the Process Source Document of the Product Sterilization System (mm/dd/yyyy)? _ _ / _ _ / _ _ _ _

Continue to Section F.

F. 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

(Attach supporting documentation and validation reports. Provide name or a brief description of attachment below.)

_____

(Continue to a)

☐ No *(Continue to F.2)*

a) Is controlling particulate size a critical factor?

☐ Yes *(Continue to b)* ☐ No *(Continue to F.2)*

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

_____

2. Does the product contain any dry ingredients that are hydrated before processing the product?

☐ Yes *(Continue to a)* ☐ No *(Continue to F.3)*

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

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

☐ Yes *(Continue to a)* ☐ No *(Continue to F.4)*

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

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

☐ Yes ☐ No

5. What is the flow correction factor used during the scheduled process? ***(Select one)***

a) ☐ 0.5 (Laminar) *(Continue to Section G)*

b) ☐ 0.83 (Turbulent) *(Continue to F.6)*

F. Product Critical Factors (Continued)

6. Answer the following questions if the flow correction factor you identified in question F.5 is 0.83 (Turbulent)

a) What is the instrument 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 the units of measure)***

_____

d) What is the specific gravity? _._ _ _ _

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

☐ Yes *(Continue to a-b)* ☐ No *(Continue to F.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 F.9)*

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

b) What is the type of binder added?

_____

9. Is syrup strength a critical factor that needs to be controlled during processing?

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

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

Continue to Section G.

G. Package Sterilization System and Supplemental Information

1. Sterilization System

a) What is the Manufacturer name and the model number of the sterilization system used to sterilize the packaging of the product?

b) What is the Process Source of the Package Sterilization System?

c) What is the date of the Process Source of the Package Sterilization System *(mm/dd/yyyy)* _ _ / _ _ / _ _ _ _

d) Supplemental Submission Identifier (SUP SID) _ _ _ _ - _ _ - _ _ - _ _ _

☐ ***(Attach Supplemental Information. Provide name or a brief description of attachment below.) (See accompanying instructions.)***

2. Sterilization System

a) What is the Manufacturer name and the model number of the sterilization system used to sterilize the packaging of the product?

b) What is the Process Source of the Package Sterilization System?

c) What is the date of the Process Source of the Package Sterilization System *(mm/dd/yyyy)* _ _ / _ _ / _ _ _ _

d) Supplemental Submission Identifier (SUP SID) _ _ _ _ - _ _ - _ _ - _ _ _

☐ ***(Attach Supplemental Information. Provide name or a brief description of attachment below.) (See accompanying instructions.)***

3. Sterilization System

a) What is the Manufacturer name and the model number of the sterilization system used to sterilize the packaging of the product?

b) What is the Process Source of the Package Sterilization System?

G. Package Sterilization System and Supplemental Information: 3. Sterilization System *(Continued)*

c) What is the date of the Process Source of the Package Sterilization System *(mm/dd/yyyy)* _ _ / _ _ / _ _ _ _

d) Supplemental Submission Identifier (SUP SID) _ _ _ _ - _ _ - _ _ - _ _ _

☐ ***(Attach Supplemental Information. Provide name or a brief description of attachment below.) (See accompanying instructions.)***

4. Sterilization System

a) What is the Manufacturer name and the model number of the sterilization system used to sterilize the packaging of the product?

b) What is the Process Source of the Package Sterilization System?

c) What is the date of the Process Source of the Package Sterilization System *(mm/dd/yyyy)* _ _ / _ _ / _ _ _ _

d) Supplemental Submission Identifier (SUP SID) _ _ _ _ - _ _ - _ _ - _ _ _

☐ ***(Attach Supplemental Information) (see accompanying instructions)***

Continue to Section H.

H. Scheduled Process

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
Process No	Hold Tube Section	Inside Diameter of Hold Tube Section	Hold Tube Section Length	Initial Temperature (*only for heating with control of flow rate before the heater)	Process Time	Temperature (at exit of final hold tube section)	Fo (F18/250)	Maximum Product Flow Rate
Number	Number	Inches	Inches	°Fahrenheit	Seconds	°Fahrenheit	Minutes	Gal/min
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I. Additional Information (Optional)

☐ 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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