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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 Food Aseptic Systems)"

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.

☐ Baby Food; ☐ 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 (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.);

☐ Gelatin, Pudding Filling for Pies, Pie Filling (liquid form ready–to-eat such as apple pie filling, etc.); ☐ Imitation Dairy (includes soy-based products);

☐ 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.);

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.);

☐ Nut Spread and Nut Topping; ☐ Other Vegetables; ☐ 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.);

☐ Soup (does not include seafood-type soups); ☐ 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

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

3. What is the form of the product? ☐ Liquid (i.e., all liquid no solids) ☐ Liquid with Solids (e.g., diced, chunks, pieces, sliced, etc.) ☐ Paste/Puree ☐ Other _____

4. What is the packing medium? ☐ Brine ☐ Cream/Sauce/Gravy ☐ Oil ☐ Syrup ☐ Water ☐ None (i.e., the product is all liquid) ☐ Other _____

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 option.

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)**
      i. ☐ 2-pieces
      ii. ☐ 3-pieces How is the side seam sealed? **(Select one)** ☐ Cemented ☐ Welded

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)**
   ☐ Other _____ **(Attach a picture or schematic)**

3. ☐ 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 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 _____

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

e) What is the predominant material used to make the lid of the container? **(Select one)**
☐ Aluminum ☐ HDPE (high-density polyethylene) ☐ HDPP (high-density polypropylene) ☐ Nylon ☐ PET (polyethylene teraphthalate) ☐ Other _____ ☐ Not Applicable
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 ☐ Other _____ ☐ Not Applicable

4. ☐ 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 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 **(Use for rectangular 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:

1. 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)**
e) What is the date of the Process Source 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)** (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 maximum dimension of the particulate size? _ _._ _ _ (**Select one)** ☐ inches ☐ millimeters

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. Is the % solids a critical factor that needs to be controlled during processing? ☐ Yes (Continue to a) ☐ No (Continue to F.4)
   a) What is the % 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)

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 _____
   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): 20_ _-_ _-_ _-_ _ ☐ **(Attach Supplemental Information) (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): 20_ _-_ _-_ _-_ _ _ ☐ **(Attach Supplemental Information) (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? ____

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

d) Supplemental Submission Identifier (SUP SID): 20_ _-_ _-_ _-_ _ _ ☐ **(Attach Supplemental Information) (see accompanying instructions)**

4. Sterilization System

a) What is the Manufacturer name and the model number of the sterilizing 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): 20_ _-_ _-_ _-_ _ _ ☐ **(Attach Supplemental Information) (see accompanying instructions)**

Continue to Section H.

H. Scheduled Process:

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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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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