

See OMB Statement on back of page.

**A. PRODUCT**

Name, Form or Style, and Packing Medium: \_\_\_\_\_

pH: \_\_\_\_ . \_\_\_\_ (Before Acidification) \_\_\_\_\_

Governing Regulation:

- low-acid (21 CFR 108.35/113)
- acidified (21 CFR 108.25/114)

Type of Submission:

- new
- replaces \_\_\_\_\_ / \_\_\_\_\_
- cancels \_\_\_\_\_ / \_\_\_\_\_

Process Use:

- scheduled
- alternate for \_\_\_\_\_ / \_\_\_\_\_
- emergency for \_\_\_\_\_ / \_\_\_\_\_

<b>FCE</b>	2 0 Y Y Y Y M M D D S S S	<b>SID</b>
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**B. PROCESSING METHOD**

NAME OF STERILIZER (MFR. & TYPE) \_\_\_\_\_

HEATING MEDIUM (e.g., Steam, water, immersion or spray, steam-air) \_\_\_\_\_

<p>1. <input type="checkbox"/> <b>Still</b></p> <p>a. <input type="checkbox"/> Horizontal    b. <input type="checkbox"/> Vertical</p> <p>Divider Plates (complete for a. or b.)</p> <p><input type="checkbox"/> None    <input type="checkbox"/> Perforated</p> <p>c. <input type="checkbox"/> Crateless</p> <p>Bottom Surface (complete for c.)</p> <p><input type="checkbox"/> Solid    <input type="checkbox"/> Perforated</p>	<p>2. <input type="checkbox"/> <b>Agitating</b></p> <p>a. <input type="checkbox"/> End over End</p> <p><input type="checkbox"/> Axial</p> <p>b. <input type="checkbox"/> Continuous</p> <p><input type="checkbox"/> Batch</p>	<p>3. <input type="checkbox"/> <b>Hydrostatic</b></p> <p><input type="checkbox"/> Inner Chain only</p> <p><input type="checkbox"/> Outer Chain only</p> <p><input type="checkbox"/> Both Inner and Outer Chain</p> <p><input type="checkbox"/> Single Chain</p> <p><input type="checkbox"/> Multiple Chain</p>	<p>4. <input type="checkbox"/> <b>Flame</b></p>	<p>5. <input type="checkbox"/> <b>Other (explain)</b></p>	<p>6. <input type="checkbox"/> <b>Acidified</b></p> <p>Maximum Equilibrium pH: ____ . ____</p> <p>Method of Acidification: _____</p> <p>Acidifying Agent: _____</p> <p>Pasteurization Method: _____</p> <p>Preservative Used: _____</p> <p>Concentration: ____ . ____, ____ . ____, ____ . ____</p>
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**CONTAINER TYPE:**

<p>1. <input type="checkbox"/> Tinplate/Steel Can    <input type="checkbox"/> 2-piece    <input type="checkbox"/> Welded</p> <p>2. <input type="checkbox"/> Aluminum Can    <input type="checkbox"/> 3-piece    <input type="checkbox"/> Cemented</p>	<p>3. <input type="checkbox"/> Glass or Ceramic</p> <p>4. <input type="checkbox"/> Flexible Pouch (specify material): _____</p>	<p>5. <input type="checkbox"/> Semirigid (specify material):    Lid _____    Body _____</p> <p>Seal Method _____</p> <p>6. <input type="checkbox"/> Other (specify): _____</p>
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PROCESS ESTABLISHMENT SOURCE (Limit entry to 30 characters) \_\_\_\_\_

DATE LAST ESTABLISHED

PROCESS RECOMMENDATIONS ATTACHED?

Y Y Y Y M M

YES     NO

**C. CRITICAL FACTORS: AS DILINEATED BY PROCESS AUTHORITY TO ASSURE COMMERCIAL STERILITY (Check or Describe)**

<p>None of the following ..... NO <input type="checkbox"/></p> <p>Maximum Water Activity (a<sub>w</sub>) ..... MW <input type="checkbox"/> ( ____ . ____ )</p> <p>Consistency / Viscosity ..... CV _____</p> <p>Value ..... ( ____ . ____ )</p> <p>Units .....</p> <p>Method Name .....</p> <p>Temperature ..... ( ____ . ____ )</p> <p>Container Position in Retort ..... CP <input type="checkbox"/></p> <p>Nesting of Containers ..... NC <input type="checkbox"/></p> <p>Fill Method (check applicable method) ..... FM _____</p> <p>Hand or Volumetric ..... <input type="checkbox"/></p> <p>Vibrating or Tumble ..... <input type="checkbox"/></p> <p>Other (specify) ..... <input type="checkbox"/></p> <p>% Solids ..... SO <input type="checkbox"/> ( ____ . ____ )</p> <p>Solid to Liquid Ratio (wt. to wt.) ..... SL <input type="checkbox"/> ( ____ . ____ )</p> <p>Drained wt./Net wt. Ratio ..... DW <input type="checkbox"/> ( ____ . ____ )</p>	<p>Arrangements of Pieces in Container ..... AP <input type="checkbox"/></p> <p>Formulation Changes ..... FC <input type="checkbox"/></p> <p>Preparation Method ..... PM <input type="checkbox"/></p> <p>Product Quality ..... PQ <input type="checkbox"/></p> <p>Matting Tendency ..... MT <input type="checkbox"/></p> <p>Layer Pack ..... LP <input type="checkbox"/></p> <p>Max. Flexible Pouch/Semirigid Container Thickness in Retort ..... MP <input type="checkbox"/> ( ____ . ____ )</p> <p>Max. Residual Air (Flexible Pouch/Semirigid Container) ..... MR <input type="checkbox"/> ( ____ . ____ ) c.c.</p> <p>Particle Size ..... PS <input type="checkbox"/></p> <p>Syrup Strength ..... SS <input type="checkbox"/> ( ____ . ____ )</p> <p>Starch Added ..... SA <input type="checkbox"/></p> <p>Max. % ..... ( ____ . ____ )</p> <p>Type .....</p> <p>Other Binder ..... OB <input type="checkbox"/></p> <p>Min. % Moisture of Dry Ingredients ..... MM <input type="checkbox"/> ( ____ . ____ )</p> <p>Other (specify) ..... OT <input type="checkbox"/></p>	<p>AP <input type="checkbox"/></p> <p>FC <input type="checkbox"/></p> <p>PM <input type="checkbox"/></p> <p>PQ <input type="checkbox"/></p> <p>MT <input type="checkbox"/></p> <p>LP <input type="checkbox"/></p> <p>MP <input type="checkbox"/> ( ____ . ____ )</p> <p>MR <input type="checkbox"/> ( ____ . ____ ) c.c.</p> <p>PS <input type="checkbox"/></p> <p>SS <input type="checkbox"/> ( ____ . ____ )</p> <p>SA <input type="checkbox"/></p> <p>( ____ . ____ )</p> <p>OB <input type="checkbox"/></p> <p>MM <input type="checkbox"/> ( ____ . ____ )</p> <p>OT <input type="checkbox"/></p>
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**D. SCHEDULED PROCESS** (Do *not* write in shaded areas -- Check appropriate box and enter numerical values on dashed lines.)

FCE: \_\_\_\_\_

SID: \_\_\_\_\_

CONTAINER DIMENSIONS				CAPACITY UNITS	SCHEDULED PROCESS <i>(Check Only One in Each Column)</i>				OTHER CRITICAL FACTORS TO ASSURE COMMERCIAL STERILITY PER SOURCE AUTHORITY								OTHER <i>(Specify)</i>			
Cont. No.	Diameter or Length	Height or Width	Height or Maximum Pouch or Semirigid Container Thickness	<input type="checkbox"/> Oz. <input type="checkbox"/> Gal. <input type="checkbox"/> ML <input type="checkbox"/> Other	Step No.	Temp (°F)	Process Time (Minutes)	Sterilization Temp (°F)	Least Sterilizing Value of the Scheduled Process	Thruput	Headspace	Speed				Maximum Weight	Minimum Net Weight	Minimum Free Liq. at Closing	Minimum Container Closing Machine Gauge Vacuum	Temp. (± 3° F)
						<input type="checkbox"/> Min.IT	<input type="checkbox"/> Process Time	<input type="checkbox"/> Process Temp.				<input type="checkbox"/> F <sub>0</sub>	<input type="checkbox"/> Other F Value	Reel Speed	Reel Diameter					
						Acidified or a <sub>w</sub> Controlled			Death Rate (z): _____	Ref. Temp.(T): _____	<input type="checkbox"/> Net <input type="checkbox"/> Gross	<input type="checkbox"/> N/A				<input type="checkbox"/> N/A	<input type="checkbox"/> N/A	<input type="checkbox"/> N/A	<input type="checkbox"/> N/A	<input type="checkbox"/> N/A
<input type="checkbox"/> Min.IT	<input type="checkbox"/> Process Time	<input type="checkbox"/> Process Temp.	<input type="checkbox"/> F <sub>0</sub>	<input type="checkbox"/> Other F Value	<input type="checkbox"/> Fill	<input type="checkbox"/> Hold Time	<input type="checkbox"/> Other	<input type="checkbox"/> IS Value				<input type="checkbox"/> Other: _____	Containers per Minute	Inches	RPM					
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COMMENTS: \_\_\_\_\_

**FOR FDA USE ONLY**

PLANT NAME / ADDRESS \_\_\_\_\_

PREFERRED MAILING ADDRESS \_\_\_\_\_

**AUTHORIZED INDIVIDUAL**

→

FULL NAME *(Please Type or Print)* \_\_\_\_\_

SIGNATURE \_\_\_\_\_

TELEPHONE NUMBER \_\_\_\_\_

DATE \_\_\_\_\_

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Food and Drug Administration  
LACF Registration Coordinator (HFS-618)  
Center for Food Safety & Applied Nutrition  
5100 Paint Branch Parkway  
College Park, MD 20740

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