

FORM APPROVED: OMB NO. 0910-0037	
EXPIRATION DATE: 8/31/2011	
See Burden Statement on page 3.	
FCE	SID

FOOD PROCESS FILING FOR ALL METHODS EXCEPT LOW-ACID ASEPTIC

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. PROCESSING METHOD

NAME OF STERILIZER (MFR. & TYPE) _____

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

<p>1. <input type="checkbox"/> Still</p> <p>a. <input type="checkbox"/> Horizontal <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"/> Agitating</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"/> Hydrostatic</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"/> Flame</p>	<p>5. <input type="checkbox"/> Other (explain) _____</p>	<p>6. <input type="checkbox"/> Acidified</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:

- 1. Tinplate/Steel Can 2-piece Welded
- 2. Aluminum Can 3-piece Cemented

- 3. Glass or Ceramic
- 4. Flexible Pouch (specify material): _____

- 5. Semirigid (specify material): Lid _____ Body _____
- Seal Method _____
- 6. Other (specify): _____

PROCESS ESTABLISHMENT SOURCE (Limit entry to 30 characters)

DATE LAST ESTABLISHED

____ / ____ / ____

PROCESS RECOMMENDATIONS ATTACHED?

YES NO

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

None of the following	NO <input type="checkbox"/>	Arrangements of Pieces in Container	AP <input type="checkbox"/>
Maximum Water Activity (a _w)	MW <input type="checkbox"/> (____)	Formulation Changes	FC <input type="checkbox"/>
Consistency / Viscosity	CV	Preparation Method	PM <input type="checkbox"/>
Value	(____)	Product Quality	PQ <input type="checkbox"/>
Units	_____	Matting Tendency	MT <input type="checkbox"/>
Method Name	_____	Layer Pack	LP <input type="checkbox"/>
Temperature	(____)	Max. Flexible Pouch/Semirigid Container Thickness in Retort	MP <input type="checkbox"/> (____)
Container Position in Retort	CP <input type="checkbox"/>	Max. Residual Air (Flexible Pouch/Semirigid Container)	MR <input type="checkbox"/> (____) c.c.
Nesting of Containers	NC <input type="checkbox"/>	Particle Size	PS <input type="checkbox"/>
Fill Method (check applicable method)	FM	Syrup Strength	SS <input type="checkbox"/> (____)
Hand or Volumetric	<input type="checkbox"/>	Starch Added	SA <input type="checkbox"/> (____)
Vibrating or Tumble	<input type="checkbox"/>	Max. %	_____
Other (specify)	<input type="checkbox"/>	Type	_____
% Solids	SO <input type="checkbox"/> (____)	Other Binder	OB <input type="checkbox"/>
Solid to Liquid Ratio (wt. to wt.)	SL <input type="checkbox"/> (____)	Min. % Moisture of Dry Ingredients	MM <input type="checkbox"/> (____)
Drained wt./Net wt. Ratio	DW <input type="checkbox"/> (____)	Other (specify)	OT <input type="checkbox"/>

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 <input type="checkbox"/> Oz. <input type="checkbox"/> Gal. <input type="checkbox"/> ML <input type="checkbox"/> Other	SCHEDULED PROCESS (Check Only One in Each Column)				OTHER CRITICAL FACTORS TO ASSURE COMMERCIAL STERILITY PER SOURCE AUTHORITY								OTHER (Specify)		
Cont. No.	Diameter or Length	Height or Width	Height or Maximum Pouch or Semirigid Container Thickness		Step No.	Temperature	Process Time	Sterilization Temperature	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	
						<input type="checkbox"/> Min.IT	<input type="checkbox"/> Process Time	<input type="checkbox"/> Process Temp.	<input type="checkbox"/> F ₀			Reel Speed	Reel Diameter	Steps Per Turn of Reel	Chain / Conveyer Speed				
						Acidified or a_w Controlled			Death Rate (z):		<input type="checkbox"/> Net				<input type="checkbox"/> Feet				
						<input type="checkbox"/> Min.IT	<input type="checkbox"/> Process Time	<input type="checkbox"/> Process Temp.	Ref. Temp.(T):	<input type="checkbox"/> Gross					<input type="checkbox"/> Carriers	<input type="checkbox"/> Drained		Temp. (± 3° F)	
						<input type="checkbox"/> Fill	<input type="checkbox"/> Hold Time								<input type="checkbox"/> Flights (per minute)	<input type="checkbox"/> Fill		----	
						<input type="checkbox"/> Center	<input type="checkbox"/> Other												
						<input type="checkbox"/> N/A	<input type="checkbox"/> N/A	<input type="checkbox"/> N/A	<input type="checkbox"/> IS Value	<input type="checkbox"/> N/A	<input type="checkbox"/> N/A			<input type="checkbox"/> N/A					
									Other: _____										
	Inches & Sixteenths	Inches & Sixteenths	Inches & Sixteenths			°F	Minutes	°F		Containers per Minute	Inches	RPM	Inches	Number	Inches	Ounces	Ounces	Ounces	In. Hg.
								
								
								
								
								
								
								
								
								
								
								
								

COMMENTS:

FOR FDA USE ONLY

PLANT NAME / ADDRESS

PREFERRED MAILING ADDRESS

AUTHORIZED INDIVIDUAL

→

FULL NAME (Please Type or Print)

SIGNATURE

TELEPHONE NUMBER

DATE

LACF Contact Information

E-mail: LACF@FDA.HHS.GOV

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**LACF REGISTRATION COORDINATOR (HFS-303)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
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College Park, MD 20740**

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