

DEPARTMENT OF HEALTH AND HUMAN SERVICES ■ Food and Drug Administration
FOOD PROCESS FILING FOR LOW-ACID ASEPTIC SYSTEMS

(USE FDA BOOKLET TITLED "ASEPTIC PACKAGING SYSTEM SUPPLEMENT")

(TYPE OR PRINT ALL INFORMATION REQUESTED, IF AN ITEM DOES NOT APPLY ENTER "NA". FILE ACIDIFIED ASEPTIC (pH 4.6 or BELOW) ON FORM 2541a)

NOTE: No commercial processor shall engage in the processing of low-acid foods unless completed Forms FDA 2541 and FDA 2541c have been filed with the Food and Drug Administration, 21 CFR 108.35 (c)(1) and (2).

FORM APPROVED: OMB No. 0910-0037
 EXPIRATION DATE: 2/28/2015

FDA USE ONLY

DATE RECEIVED BY FDA

| <p>1. FCE _____</p> <p>2. ESTABLISHMENT NAME</p> <p>ADDRESS (No. and Street)</p> <p>CITY STATE</p> <p>ZIP (OR OTHER POSTAL CODE) COUNTRY</p> <p>3. SID 2 0 - - / Y Y Y Y M M D D S S S</p> <p>4. <input type="checkbox"/> NEW <input type="checkbox"/> CANCELS <input type="checkbox"/> REPLACES Y Y Y Y M M D D S S S</p> <p>5. <input type="checkbox"/> SCHEDULED <input type="checkbox"/> ALTERNATE FOR Y Y Y Y M M D D S S S</p> <p>6. SUP SID 2 0 - - / Y Y Y Y M M D D S S S</p> | <p>7. PRODUCT NAME, FORM OR STYLE, AND PACKING MEDIUM</p> <p>8. NAMES OF STERILIZING SYSTEMS</p> <p>a. Product¹</p> <p>b. Packaging</p> <p>9. PROCESS ORIGIN</p> <table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th>No.</th> <th>Source for 8.a. and 8.b.</th> <th>Date (mm/yyyy)</th> </tr> </thead> <tbody> <tr> <td>a.</td> <td></td> <td></td> </tr> <tr> <td>b.</td> <td></td> <td></td> </tr> </tbody> </table> <p>10. CONTAINER TYPE (Check one)</p> <p>a. <input type="checkbox"/> Tinplate or Steel Can b. <input type="checkbox"/> Aluminum Can c. <input type="checkbox"/> Glass</p> <p>d. <input type="checkbox"/> Other (Specify below and in item 22 if necessary)</p> | No. | Source for 8.a. and 8.b. | Date (mm/yyyy) | a. | | | b. | | |
|---|---|----------------|--------------------------|----------------|----|--|--|----|--|--|
| No. | Source for 8.a. and 8.b. | Date (mm/yyyy) | | | | | | | | |
| a. | | | | | | | | | | |
| b. | | | | | | | | | | |

| 11. MAXIMUM WATER ACTIVITY ² | 12. pH | | 13. MAXIMUM CONSISTENCY OR VISCOSITY IN CENTIPOISES OR APPROPRIATE UNITS | | | | 14. SPECIFIC GRAVITY AT 77 ± 2°F | 15. INSIDE DIAMETER OF HOLDING TUBE (Inches) | 16. HOLDING TUBE LENGTH (Inches) |
|---|--------|-------------------|--|---------------------|-----------------|-------|----------------------------------|--|----------------------------------|
| | Normal | Max. ³ | Value at 77±2°F | Value at Other Temp | Other Temp (°F) | Units | | | |
| 0. | . | . | . | . | . | . | . | . | . |

| 17. OTHER CRITICAL CONTROL FACTORS (Check all that apply) | 18. CONTAINER DIMENSIONS (Inches and Sixteenths) | | | | 19. SCHEDULED PROCESS | | | | 20. MAXIMUM FOOD FLOW RATE (gal / min) | 21. THRUPUT (containers / minute) | FOOTNOTES |
|---|--|--------------------|-----------------|--------|--|------------|-----------|--|--|-----------------------------------|--|
| | No. | Diameter or Length | Height or Width | Height | Minimum Initial ⁴ Temp (°F) | Time (sec) | Temp (°F) | Least Sterilizing Value (F ₀) ⁵ | | | |
| 61 <input type="checkbox"/> Percent Solids | 1 | | | | | . | | . | . | | 1 For steam injection, enter volume increase and thermal expansion factors in 22. 2 If reduced water activity is used as an adjunct to the process, specify the maximum water activity. 3 Where acidification is followed for normally low-acid fruits, vegetables or vegetable products for the purpose of thermal processing, specify the maximum finished product equilibrium pH. 4 If a critical factor is in the process. 5 Or equivalent scientific basis of process adequacy. |
| 62 <input type="checkbox"/> Ratio of Solids to Liquids | 2 | | | | | . | | . | . | | |
| 63 <input type="checkbox"/> Syrup Strength | 3 | | | | | . | | . | . | | |
| 68 <input type="checkbox"/> Method of Preparation | 4 | | | | | . | | . | . | | |
| 70 <input type="checkbox"/> Formulation | 5 | | | | | . | | . | . | | |
| 71 <input type="checkbox"/> Rehydration (specify method in 22) | 6 | | | | | . | | . | . | | |
| 72 <input type="checkbox"/> Particulates (specify maximum size in 22) | | | | | | . | | . | . | | |
| 73 <input type="checkbox"/> Other (specify in 22) | | | | | | . | | . | . | | |

| | | | |
|----------------------------|--|-----------|--|
| <p>22. COMMENTS</p> | AUTHORIZED COMPANY REPRESENTATIVE | | |
| | NAME (Type or Print) | TITLE | |
| SIGNATURE | DATE | PHONE NO. | |

LACF Contact Information

E-mail: LACF@FDA.HHS.GOV

Telephone: 240-402-2411

**LACF REGISTRATION COORDINATOR (HFS-303)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF ADDRESS BELOW.

The burden time for this collection of information is estimated to average .75 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
1350 Piccard Drive, Room 400
Rockville, MD 20850

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."