

FOOD PROCESS FILING FOR ALL METHODS EXCEPT LOW-ACID ASEPTIC

(Use FDA booklet titled: "Instructions for Establishment Registration and Process Filing for Acidified and Low-Acid Canned Foods" for completing Form FDA 2541a.)

FORM APPROVED: OMB NO. 0910-0037
EXPIRATION DATE: 8/31/05

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 ____ / ____

FCE

SID

2 0 ____ / ____
Y Y Y Y M M D D S S S

B. PROCESSING METHOD

NAME OF STERILIZER (MFR. & TYPE) _____

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

1. Still, 2. Agitating, 3. Hydrostatic, 4. Flame, 5. Other, 6. Acidified. Includes sub-options for still types, agitation methods, hydrostatic types, flame, other explanations, and acidification details like pH and preservatives.

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

Y Y Y Y M M

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

Table of critical factors including MW, CV, CP, NC, FM, SO, SL, DW, AP, FC, PM, PQ, MT, LP, MP, MR, PS, SS, SA, OB, MM, OT with checkboxes and input fields.

Public reporting burden for this collection of information is estimated to average .333 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:

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

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 control number.