Instructions for Paper Submission of Form FDA 2541g (Food Process Filing for Low-Acid Aseptic Systems)

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I. Introduction

This document is intended for:

- Commercial processors who manufacture, process, or pack thermally processed low-acid foods packaged in hermetically sealed containers (historically referred to as "low-acid canned foods" or "LACF")[1];

- Persons who are authorized to act on behalf of such commercial processors[2].

Commercial processors who manufacture, process, or pack LACF are subject to the registration requirements of 21 CFR 108.35(c)(1), as well as the process filing requirements of 21 CFR 108.35(c)(2). These provisions require two basic types of submissions:

- Food Canning Establishment Registration using Form FDA 2541; and
- Process filings using the following forms:
  - Form FDA 2541d (Food Process Filing for Low-Acid Retorted Method)
  - Form FDA 2541f (Food Process Filing for Water Activity /Formulation Control Method)
  - Form FDA 2541g (Food Process Filing for Low-Acid Aseptic Systems

This document provides detailed instructions on how to submit process filings by using a *paper* Form FDA 2541g (Food Process Filing for Low-Acid Aseptic Systems). Form FDA 2541g is intended for low-acid foods (as defined in 21 CFR 113.3(n))where the growth of microorganisms is controlled through the application of heat to foods and

[1] Although some hermetically sealed containers (e.g., pouches and glass bottles) used to package thermally processed low-acid foods generally would not be viewed as "cans," the term "low-acid canned foods" has been used for decades as a shorthand description for "thermally processed low-acid foods packaged in hermetically sealed containers," and we continue to use that term (and its abbreviation, LACF) for the purposes of this document.

[2] Individuals who are authorized to act on behalf of commercial processors may do so for more than one commercial processor. Reference 1 addresses our electronic system for submitting process filing and identifies the responsibilities of each type of authorized user for that system.

where the processing involves use of aseptic processing and packaging (as defined in 21 CFR 113.3(a)).

This document does not provide:

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- Instructions for *electronic* submission of Form FDA 2541g (Food Process Filing for Low-Acid Aseptic Systems);
- Instructions for submitting process filing Form FDA 2541f in either electronic or paper format;
- Instructions for submitting Form FDA 2541d (Low-Acid Retorted Method) in either electronic or paper format;
- Instructions for submitting Form FDA 2541e (Acidified Foods) in either electronic or paper format; or
  Instructions for submitting plant registration Form FDA 2541 in either electronic or paper format.

For additional information about registration and process filing for commercial processors of LACF, see our guidance entitled "Guidance for Industry: Submitting Form FDA 2541 (Food Canning Establishment Registration) and Forms FDA 2541d, FDA 2541e, FDA 2541f, and FDA 2541g (Food Process Filing Forms) to FDA in Electronic or Paper Format" (Ref. 1 and the appendices in Reference 1.) For a list of abbreviations used in this document and other FDA documents relating to commercial processors who manufacture, process, or pack LACF and that are subject to 21 CFR Part 108, refer to Appendix D.

II. How to Submit Process Filing Form FDA 2541g by Paper

A. General Information

The paper Form FDA 2541g contains 9 sections (Sections A through I).

- All mandatory fields on Form FDA 2541g must be completed. Only three sections include optional information:
  - Section A, Question 1 (Food Product Group) is optional.
  - Section D, Question 3 (Net Weight (Optional)) is optional.
  - Section I, Additional Information (Optional) is optional.

- When you manufacture, process, or pack a product in more than one container size or type, you are required to submit a separate Form FDA 2541g for each container size and type.
- You may report multiple forms of the product (e.g., Liquid (i.e., all liquid no solids); liquid with solids (diced, chunks, pieces, etc.); paste/puree) on the same Form FDA 2541g, provided that:
  - Other factors (e.g., container type or size) do not require separate filing; and

    - The process information you provide in Section H of Form FDA 2541g applies to each product variation. If the heat transfer rates are different for each product variation, the process for the slowest heating formulation with the fastest flow (laminar correction factor) must be filed. The comment section of the filing form should state on which formulation product the process is based.
- You may report multiple product packing mediums on the same Form FDA 2541g provided that:
    - Factors other than "product packing medium" (e.g., container type or size) do not require separate filing; and

    - The process information you provide in Section H of Form FDA 2541g applies to each product variation. If the heat transfer rates are different for each product variation, the process for the slowest heating formulation with the fastest flow (laminar correction factor) must be filed. The comment section of the filing form should state on which formulation product the process is based.

- You may report multiple products with minor formulation changes (e.g., drinks formulated with different flavors) on the same Form FDA 2541g provided that:
    - Other factors (e.g., container type or size) do not require separate filing; and
    - The process information you provide in Section H of Form FDA 2541g applies to each formulation of the product. If the heat transfer rates are different for each product formulation variation, the process for the slowest heating formulation with the fastest flow (laminar correction factor) must be filed. The comment section of the filing form should state on which formulation product the process is based.

- Brand names of products generally should not be part of the Product Name. However, you may need to include the brand name as part of the Product Name if it is necessary to distinguish products that are produced using different scheduled processes. You need not submit a separate Form FDA 2541g for each brand name of a product that is manufactured, processed, or packed under more than one brand name if the scheduled process for each brand is exactly the same.

An aseptic processing system includes a product sterilization system and a packaging sterilization system and may include a surge tank system. In Section E of Form FDA 2541g, you provide some information about the product sterilization system. You provide the remaining information about the product sterilization system, and information about a surge tank system if you use one, in a "Supplemental Submission" (see Appendix C). With respect to information about the packaging sterilization system, you likewise provide some information on Form FDA 2541g (in this case, in Section G), and the remaining information about the packaging sterilization system in the "Supplemental Submission."

When preparing separate forms that contain much of the same information (such as for a product that you manufacture, process, or pack in multiple container sizes), you may save time by using photocopying. Specifically, you may enter the information that applies to

all the products, photocopy the form, and then complete the product-specific information on the photocopies. Each submitted form must be complete. Importantly, each submitted form must have a unique SID (see Step One) and must have an original (not photocopied) signature of an authorized company representative.

We recommend that the authorized representative make and keep a copy of each process filing form.

B. Step 1: Top of Form – Food Canning Establishment Number and Submission Identifier

Provide the FCE number and SID at the top of Form FDA 2541g, before Section A. Leave the "Date Received by FDA" blank (this is for FDA internal use only).

1. Food Canning Establishment (FCE) Number:

We assign a Food Canning Establishment (FCE) number to each physical processing facility that registers using Form FDA 2541 (Ref. 1). Enter the five digit FCE number we provide for the specific establishment (processing location) where the product(s) are manufactured, processed, or packed after you register that establishment using Form FDA 2541. If you are submitting a process filing at the same time as you are registering your establishment for the first time, you may leave the FCE number blank.

2. Submission Identifier (SID):

Each process filing is identified by a unique Submission Identifier (SID). The SID is a unique number associated with each new process filing. You assign the SID. The combination of the FCE number and the SID identifies a specific process filing form.

The SID is a combination of:

- (1) The date (i.e., year, month, and day of the month) that a process filing form is created; and
- (2) A sequence number that would distinguish multiple forms created on the same date. The sequence number starts with 001 and continues (002, 003) for as long as necessary to uniquely identify all forms created on the same date.

If you submit multiple types of process filing forms on the same date (e.g., if you submit three Forms FDA 2541g and three Forms FDA 2541f on the same date), the sequence number would increase by 001 for each created form rather than begin again at 001 for each type of form (see examples immediately below).

When you submit paper forms, you assign the SID and include it on the form using the following format:

YYYY-MM-DD/SSS

Where:

YYYY represents the calendar year (e.g., 2013, 2014)

MM represents the month (e.g., 02 for February, 10 for October)

DD represents the day of the month (e.g., 02, 19, 30)

SSS represents the assigned sequence number (e.g., 001, 002, 003).

Examples of SIDs include:

2013-02-22/001: The first Form FDA 2541g created on February 22, 2013

2013-02-22/002: The second Form FDA 2541g created on February 22, 2013

2013-02-22/003: The third Form FDA 2541g created on February 22, 2013

2013-02-22/004: The fourth process filing form, this one a Form FDA 2541f, created on February 22, 2013

2013-02-22/005: The fifth process filing form, this one a Form FDA 2541f, created on February 22, 2013

2013-02-22/006: The sixth process filing form, this one a Form FDA 2541f, created on February 22, 2013

C. Step 2 – Section A. Product Information

1. Food Product Group (Optional):

We request information about "Food Product Groups" to help us understand the nature of your products. The information you provide helps FDA prioritize which commercial processing facilities to inspect. The Food Product Group is optional information (i.e., you are not required to identify the Food Product Group.) If you choose to fill in this information and there is no single best Food Product Group applicable to the product, select "Other."

2. Enter Product Name.

Describe the actual food commodity or formulated food in the container (e.g., carrot juice, pumpkin puree, chicken broth, cheese sauce).

- If the product is named in a foreign language, provide its English equivalent first and then provide the foreign language name in parentheses (e.g., cheese sauce (sauce au fromage)).

  The product name may include scientific names. When a scientific name is in Latin, the product name should also include the common English translation or description of the scientific name (e.g., potato soup (Solanum Tuberosum pulmentum)).

- Brand names should not be part of the product name unless a brand name is necessary to distinguish products that are produced using different scheduled processes.

Some product names may include qualifying terms that identify unique species, processing methods, or organoleptic or visual properties. Some products may be compartmentalized, and include multiple types of foods. For such products, specify these unique properties. If, however, you are submitting the same Form FDA 2541g for multiple products with minor formulation indicate those minor formulation differences with the product name. (See section II.A. of these instructions.) For example, if you are submitting the same Form FDA 2541g for a beverage that you make in both strawberry and banana flavor, indicate those flavors as part of the product name. Some examples of product names:

- Enter "Coconut Water (banana or strawberry)" (when submitting one form for both formulas), not "Coconut Water" and not "Water"
- Enter "Energy drink (chocolate flavors)," not "Energy drink"
- Enter "Cheese Sauce (with Jalapeño pieces)," not "Cheese Sauce"
- Enter "Milk (1%, 2%, or whole)," (when submitting one form for multiple milk products), not "Milk"

3. What is the form of the product?

The product form relates to the shape or appearance of the product itself (e.g., whether the liquid also contains solids, and whether the product is a paste or puree) rather than the characteristics of the container.

Select one or more product forms listed on the filing form. If the product form is all liquid with no solids, select "Liquid (i.e., all liquid no solids). You may report multiple forms of the product on the same Form FDA 2541g with the caveats discussed in section II.A of this document. If none of the product forms listed on the form apply, select "Other" and enter the product form in the space provided.

4. What is the packing medium?

In general, "packing medium" refers to the liquid portion(s) of a product when the liquid is added over, or added to, the solid portion(s) of a product. You may report multiple product packing mediums on the same Form FDA 2541g with the caveats discussed in section II.A of this document.

Select one or more packing mediums listed on the form. If a product is all liquid, select "None." If none of the choices are applicable, select "Other" and enter the packing medium in the space provided.

D. Step 3 – Section B. Governing Regulation

Form FDA 2541g only applies to low-acid aseptic systems, which are regulated pursuant to 21 CFR 108.35 and 21 CFR Part 113. Refer to Ref. 5 of this document. Form FDA

2541g does not apply to an acidified food that has a finished equilibrium pH of 4.60 or below, even if the acidified food is packaged using an aseptic system. Use Form FDA 2541e for an acidified food packaged using an aseptic system. Because Form FDA 2541g only applies to low-acid foods, Form FDA 2541g identifies the governing regulations and you do not need to add any information to Section B.

E. Step 4 – Section C. Container Type

Each different container type and each different size of the same container type should be filed as a separate Form FDA 2541g. Therefore, for any Form FDA 2541g that you submit, select a single container type. For additional technical information about container types, refer to Appendix – A, Container Types and Shapes.

1. Aluminum/Tinplate/Steel Can

The first container type listed on Form FDA 2541g is for a container of all non-flexible metal (i.e., aluminum,[3] tinplate, or steel can). Do not select Aluminum/Tinplate/Steel Can if the container combines metal in one layer with other materials (e.g., paperboard or a polymer) in other layers.[4]

a) What is the shape of the container?

Select the shape that best applies to the container. If the container is asymmetrical in shape, select "Irregular", attach a picture or schematic, and in the space provided enter the document name for the attachment. If none of the shapes apply, select "Other", attach a picture or schematic, and in the space provided enter the document name for the attachment.

b) How many pieces are used to construct the container?

A 2-piece container is a container where one end is made as part of the can body. There is no side seam and only one end is attached through the formation of a double seam.

A 3-piece container consists of a can body and two attached ends. A 3-piece container can be identified by the presence of a side seam. The side seam runs the length of the cylinder from one end to the other. Side seams are either cemented or welded.

You may select "2-piece container" or "3-piece container" or both, as applicable.

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[3] Note that we consider an aluminum can to be a non-flexible metal container rather than a semi-rigid container.

[4] Note that we consider a combination of metal and other material containers to be a retortable paperboard or semi-rigid container.

2. Flexible Pouch

The second container type listed on Form FDA 2541g is for a container of flexible material.

A flexible pouch is a food container that has no fixed shape. Its final shape is defined by the product placed inside it during the filling and sealing process. It is constructed of flexible panels composed of laminated polymers. The composition of laminated polymers varies depending on the food product, the processing method, and the intended use. Some flexible pouches contain a foil layer.

a) What is the shape of the container?

Select the shape that applies to the container. For "Irregular" or "Other" shapes, attach a picture or schematic of the pouch, and in the space provided enter the document name for the attachment.

3. Semi-Rigid

The third container type listed on Form FDA 2541g is for a container of semi-rigid material.

A semi-rigid container is a container where the shape of the container is not altered by filling of product at atmospheric pressures---but can be altered by additional external pressure.

a) What is the shape of the container?

Select the shape that best fits the container. For "Irregular" or "Other" shapes, attach a picture or schematic, and in the space provided enter the document name for the attachment.

b) Is this a single-piece container?

If the container is made of one piece of material and the ends are fused, select "Yes" and continue to question d. Otherwise, select "No" and continue to question c.

c) Is this a compartmentalized container?

Compartmentalized containers are containers that hold more than one food product (e.g., baby food consisting of corn and baby food consisting of green beans where the corn and green beans are held in separate sections within a single container) and the food is processed in the single container.

If the container consists of more than one compartment and the compartments contain different food products, select "Yes" and identify the number of compartments. Otherwise, select "No."

d) What is the predominant material used to make the body of the container?

Select the material that, based on weight, is the predominant material used to make the container stock. If you select "Other," enter the information next to "Other."

If you selected "Yes" to question 3.b (indicating that you use a single-piece container), skip the remaining questions under this section and continue to Section D. Otherwise, continue with questions e and f.

e) What is the predominant material used to make the lid of the container?

Select the material that, based on weight, is the predominant material used to make the lid stock. If you select "Other," enter the information next to "Other." If the container is a web fed paperboard brick pack, without a lid, select "Not Applicable."

f) How is the lid sealed to the body of the container?

Select the appropriate mechanism for how the lid is sealed to the body of the container. If you select "Other," enter the information next to "Other." If the container is a web fed paperboard brick pack, without a lid, select "Not Applicable."

4. Other Container

The fourth container type listed on Form FDA 2541g is for a container of a type other than the ones listed above.

Select "Other" when none of the container types listed on the form applies and enter the container type.

a) Attach a schematic or picture of the container and in the space provided enter the document name for the attachment.

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 material that, based on weight, is the predominant material used to make the lid stock. 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. If the container does not have a lid, specify Not Applicable.

F. Step 5 – Section D. Container Size

Section D includes information on Container Size. You are required to complete D.1 (Dimensions); 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. Products come in a variety of container shapes (see section II.E of these instructions for information about container shapes). For cylindrical (including bowl and oval) shapes, select "a" to report the container size. For rectangular (including trays) shapes, irregular shapes, or pouches, select "b" to report the container size. Report container dimensions in English units (number of whole inches and sixteenths of an inch).

Refer to Appendix – B, Container Dimension Measurements for examples.

1. Dimensions:

a) Diameter and Height.

Enter information for Diameter and Height only for cylindrical (including bowl and oval) shaped containers.

b) Length, Width, and Height/Thickness.

Enter information for Length, Width, and Height/Thickness for container shapes other than cylindrical.

When entering dimensions for diameter, length, width, and height/thickness, express the dimensions by creating a round number that is a code reflecting the dimensions in inches. The first part of the code represents the whole number of inches and the last two digits represent the fraction of an inch in sixteenths. For example:

- If the dimension is 12 and 8/16 inches, create the code from 12 and 08 – i.e., 1208.
- If the dimension is 5 and 15/16 inches, create the code from 5 and 15 - i.e., 515.
- If the dimension is 3 and ¾ inches, first express the ¾ inches in sixteenths - i.e., 12/16. Then create the code from 3 and 12 - i.e., 312.
- If the dimension is 4 inches, create the code from 4 and 00 - i.e., 400.
- If the dimension is 4 and 1/8 inches, first express the 1/8 inches in sixteenths - i.e., 2/16. Then create the code from 4 and 2 - i.e., 402.

Rounding may be necessary for sizes that are less than one sixteenth of an inch. Rounding can be up or down depending on the measurement. If the measurement is closer to the "higher" sixteenth, round up; if the measurement is closer to the "lower" sixteenth, round down. For example:

- If the diameter is 3 and 7/16 inches and the width is 2 inches and 1/4 of one 16th inches, the rounded dimensions will be 307 x 200
- If the diameter is 4 5/16 inches, the width 3 and 1/16 inches, and height is 0.906 (14/16ths and 1/2 of one 16th of an inch), the rounded dimensions will be 405 x 301 x 015

2. Volume:

Enter the volume using a maximum of three digits before the decimal point and one digit after the decimal point and select the applicable units.

3 Net Weight (Optional):

This question provides the opportunity for you to include the net weight of your product. Although you are not required to enter this information on this filing form, entering the information can help FDA inspectors examining product in matching a product under examination to the product described in this filing form.

Only the quantity of food in the container or package is stated in the net quantity statement. Do not include the weight of the container, or wrappers and packing materials. To determine the net weight, subtract the average weight of the empty container, lid and any wrappers and packing materials from the average weight of the container when filled with food.

Enter the net weight in ounces if you choose to provide this optional information using a maximum of three digits before the decimal point and two digits after the decimal point.

G. Step 6 – Section E. Product Processing Method

Processing method is a general description of how the food product is rendered commercially sterile before being aseptically filled into the container. Note that in Section E you provide information only about the processing method (including the sterilization system) for the product itself and not about the sterilization system for the package. You provide information about the package sterilization system in Section G.

1. Product Sterilization System

a) What is the finished equilibrium pH of the product after processing?

Enter the representative pH of the product after processing using a maximum of two digits before the decimal point and two digits after the decimal point. We consider this pH value to be an average of a range between the low and high pH of the standard product. In instances where there is no decimal value, the decimal portion will be two zeros.

b) Heating method

Answer the following questions regarding your heating method.

Question b.i: Direct Heating or Indirect Heating?

The product may be heated directly by steam introduced into the product stream or indirectly by steam/water separated from the product by a physical barrier. If steam is introduced directly into the product stream, select “Direct Heating.” If steam/water is

separated from the product by a physical barrier (e.g., plate, tube, shell, coil), select "Indirect Heating."

Question b.ii: What is the Thermal Expansion Coefficient?

Thermal expansion is the tendency of matter to change in volume in response to a change in temperature. The degree of expansion divided by the change in temperature is called the material's coefficient of thermal expansion. Enter the value using one digit before the decimal point and two digits after the decimal point.

Question b.iii: Where is the product flow rate controlled?

Before the heater: Select "Before the heater" if the product flow rate is controlled before the heater. If you select "Direct heating" under Section E.1.b.i, continue to question E.1.b.iii.1. If you selected "Indirect heating" under Section E.1.b.i, continue to question E.1.c.

After the heater: Select "After the heater" if the product flow rate is controlled after the heater and continue to question c.

Question b.iii.1: Volume Expansion Factor: You should only answer this question if you answered "Before the heater" under Section E.1.b.iii and "Direct Heating" under Section E.1.b.i. Volume expansion is the amount of expansion that occurs due to the addition of steam to the product during direct heating. When direct heating is selected and the flow rate is controlled before the heater, enter the volume expansion factor using one digit before the decimal point and two digits after the decimal point.

c) What is the Manufacturer's name and the model number of the Product Sterilization System?

Enter the manufacturer's name and the model number of the product sterilization system.

d) What is the Process Source of the Product Sterilization System?

The process source is the individual or entity (e.g., organization, company, individual, university, or other entity) that establishes the scheduled process. In the case of low-acid foods processed using aseptic systems, the scheduled process identifies the product sterilization system. Scheduled processes for low-acid foods must be established by qualified persons having expert knowledge of thermal processing requirements for low-acid foods in hermetically sealed containers and having adequate facilities for making such determinations.

Enter the name of the process source who scientifically established the scheduled process(es) for the product sterilization system, attach the support documentation containing the process recommendations (e.g., letter, bulletin, scientific paper), and in the

space provided enter the document name for the attachment. You may refer to 21 CFR 113.83 for more detailed requirements concerning establishing scheduled processes. Below, we provide some examples of how to name the process source of the product sterilization system.

- If the process was established by your facility, enter the facility's name.

- If the process was established by an organization, individual, university or other entity, enter the name of that entity (followed by the name of an individual, as appropriate).

- If the process was established by a reference source document or publication, enter the reference source document.

e) What is the date of the Process Source Document of the Product Sterilization System?

Enter the date of the product sterilization system process source document that is attached in month/day/year format.

H. Step 7 – Section F. Product Critical Factors

In Section F of the form, you provide information about critical factors for the product. (Note that this is distinct from the Supplemental Submission Attachment for Form FDA 2541g,which is part of Section G of the form, in which you provide information about critical factors associated with the product sterilization system, any aseptic surge tank, and the package sterilization system.) Under 21 CFR 113.3(f), critical factor means any property, characteristic, condition, aspect, or other parameter, variation of which may affect the scheduled process and the attainment of commercial sterility. Part 113 requires that the processing of low-acid canned foods be done in a manner that ensures that commercial sterility is achieved.

1. Does the product contain particulates?

Particulates are any solid or semi-solid pieces that may erode or diminish during processing, but are still discernable in the finished product. If the product contains particulates, select "Yes," provide the support documentation and validation reports, and continue to question F.1.a. Otherwise, select "No" and continue to question F.2.

a) Is controlling particulate size a critical factor?

Some particulates are naturally limited in size (e.g., rice, beans, peas, corn kernels) or mechanically modified in size (e.g., cut, diced). If failing to control the size could impact the thermal process or heat transfer to the particle, select "Yes" and continue to question F.1.b. Otherwise, select "No" and continue to question F.2.

b) What is the shape and maximum dimension of the particulate size to be controlled? If more than one, list all that apply.

Enter the dimensions (maximum and/or minimum, as applicable) of the particle size to be controlled, its unit of measure, and the food component to which the limitation applies (e.g., "cuts ≥1/4 inch"; shrimp sizes such as "small"; "minimum slice thickness ≥3/16 inch"; fish balls "maximum diameter ¾ inch"; stuffed pasta tube "maximum 2 inch length by ½ inch diameter" etc.).

2. Does the product contain any dry ingredients that are hydrated before processing the product?

If your product contains dry ingredients that are hydrated before processing the product, select "Yes" and continue to question F.2.a. Otherwise, select "No" and continue to question F.3.

a) What is the minimum % moisture of the hydrated dry ingredients before processing?

For the dry ingredients that are hydrated before processing, enter the minimum percent moisture of the ingredients after they have been hydrated but before the product has been processed. Enter the percent moisture using a maximum of two digits before the decimal point and two digits after the decimal point.

3. Does the % total solids affect the heating of the product during processing?

In some processes, the amount of solids in the product can impact the thermal process. If the percent total solids affect the thermal process, select "Yes" and continue to question F.3.a. Otherwise, select "No" and continue to question F.4.

a) What is the % total solids?

Enter the maximum percent total solids in the product that is critical to the process using a maximum of two digits before the decimal point and two digits after the decimal point.

4. Is the finished equilibrium pH of the product after processing (identified in Section E) critical to the process?

In some instances, the thermal process delivered to a low-acid food product is calculated based upon the pH of the finished product. If pH is critical to the thermal process of the product, select "Yes." Otherwise, select "No."

5. What is the flow correction factor used during the scheduled process?

Select one of the two available choices. If the product exhibits a laminar flow/transitional flow (Re < 4000), select "0.5 (Laminar)" and continue to Section G. If the product exhibits a turbulent flow (Re > 4000), select "0.83 (Turbulent)" and continue to question 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?

Enter the instrument used (e.g., Brookfield).

b) What is the temperature when you measure the consistency/viscosity?

To obtain an accurate measurement of consistency/viscosity, you should make your measurement at the temperature recommended by the manufacturer of the instrument used to measure the consistency/viscosity. Enter the product temperature in degrees Fahrenheit when you measure the consistency/viscosity using a maximum of three digits before the decimal point and one digit after the decimal point.

c) What is the consistency/viscosity? What is the unit of measure?

Enter the measured value using a maximum of three digits before the decimal point and two digits after the decimal point and select the appropriate units measured. If you select "Other," enter the units of measure next to "Other."

Examples of other units of measure:

- Pascal-second (Pa.s)
- Saybolt Seconds Universal (SSU)
- Stokes (St)

d) What is the specific gravity?

Enter the specific gravity using one digit before the decimal point and four digits after the decimal point.

7. Is starch added to maintain consistency/viscosity of the product?

If starch is added to achieve a desired consistency/viscosity, select "Yes" and continue to questions F.7.a-F.7.b. Otherwise, select "No" and continue to question F.8.

a) What is the maximum % starch added?

Enter the maximum percent starch of the total product formula weight using a maximum of two digits before the decimal point and two digits after the decimal point.

b) What type of starch is added?

Enter the type of starch added to the product.

Examples of starch types:

- Modified Corn starch

- Potato starch

8. Are other binders added?

If binders other than starch are added to the product to achieve a desired consistency/viscosity, select "Yes" and continue to questions F.8.a-F.8.b. Otherwise, select "No" and continue to question F.9.

a) What is the maximum % binder added?

Enter the maximum percent binder of the total product formula weight using a maximum of two digits before the decimal point and two digits after the decimal point.

b) What type of binder is added?

Enter the type of binder added to the product.

Examples of binder types:

- Gelatin
- Xanthan Gum

9. Is syrup strength a critical factor that needs to be controlled during processing?

Syrups are included as ingredients in many products to achieve a desired taste and sensory quality. If adding syrups is critical to how the product heats, select "Yes" and continue to question F.9.a. Otherwise, select "No" and continue to Section G – Package Sterilization System and Supplemental Information.

a) What is the brix measurement?

Degree Brix is the % sugar, by weight, of an aqueous solution. Enter the maximum degrees (Brix) to the nearest one decimal place of a degree (e.g., 30.0) using a maximum of two digits before the decimal point and one digit after the decimal point.

I. Step 8 – Section G. Package Sterilization System and Supplemental Information

In Section G of the form, you provide (1) information about the package sterilization system and (2) an attachment called a "Supplemental Submission Attachment for FDA Form 2541g" ("Supplemental Submission"). With respect to questions G.1.a.-G.1.c, you may enter information for up to four individual package sterilization systems. Refer to Appendix C for more information about the Supplemental Submission.

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?

Enter the Manufacturer's name and the model number of the sterilization system used to sterilize the packaging and used to fill the product while in the sterile environment.

b) What is the Process Source of the Package Sterilization System?

The process source is the individual or entity (e.g., organization, company, individual, university, or other entity) that establishes the scheduled process for the package sterilization system. Scheduled processes for aseptic package sterilization systems must be established by qualified persons having expert knowledge of thermal processing requirements for low-acid foods in hermetically sealed containers and having adequate facilities for making such determinations.

Enter the name of the process source who scientifically established the scheduled process(es) for the package sterilization system, attach the support documentation containing the process recommendations (e.g., letter, bulletin, scientific paper), and in the space provided enter the document name for the attachment. You may refer to 21 CFR 113.83 for more detailed requirements concerning establishing scheduled processes. Below, we provide some examples of how to name the process source of the package sterilization system.

- If the process was established by your facility, enter the facility's name.

- If the process was established by an organization, individual, university, or other entity, enter the name of that entity (followed by the name of an individual, as appropriate).

- If the process was established by a reference source document or publication, enter the reference source document.

c) What is the date of the Process Source Document of the Package Sterilization System?

Enter the date (using the format month/day/year) of the process source of the package sterilization system.

d) Supplemental Submission Identifier (SUP SID): ____-__-__-___

The Supplemental Submission Identifier (SUP SID) is a code identifying the "Supplemental Submission" that you submit as a supplement to Form FDA 2541g. The Supplemental Submission serves to provide a more in-depth description of the sterilization system. You may attach up to four Supplemental Submissions to a single Form FDA 2541g if a single product sterilization system feeds into more than one packaging sterilization system. See "Appendix C, Supplemental Submission Attachment for FDA Form 2541g" for instructions on how to create a SUP SID code for the Supplemental Submission, information about what to include in a Supplemental Submission, and recommendations for software programs that can help you present the information.

J. Step 9 – Section H. Scheduled Process

Under 21 CFR 113.3(r), scheduled process means the process selected by the processor as adequate under the conditions of manufacture for a given product to achieve commercial sterility. The scheduled process, which is the process established by a qualified process source as described in sections II.G.1.d and II.I.1.b of this document, may be in excess of what is necessary to ensure destruction of microorganisms of public health significance.

List each process on a single line, except if your processing system utilizes a hold tube that varies in internal diameter along the length of the hold tube. If your hold tube has more than one section and each section has a different internal diameter, enter information about each hold tube section on a separate line. Refer to Figure 3, which shows how multiple hold tube sections are identified.

1. Column 1. Process No.

Each process has its own process number. Enter the number 1 in the first row, the number 2 in the second row, and continue entering numbers in increments of 1 for each scheduled process that you list. The process number increases by increments of 1 regardless of the number of holding tube sections in each scheduled process.

2. Column 2. Hold Tube Section

If your hold tube has the same internal diameter for its entire length, enter the number 1. If the internal diameter varies along the length of the hold tube, enter 1 on the first line, 2 on the second line, and continue entering numbers in increments of 1 for each variation in internal diameter along the length of the hold tube. We list below some examples of how to provide this information.

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
1	1	1.90	500.000	_ _ _._	5.26	282.0	5.00	35.00

Figure 1 - Single Process, Single Hold Tube Section and Fo

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
1	1	1.90	500.000	_ _ _._	5.26	282.0	5.00	35.00
2	1	1.90	500.000	_ _ _._	4.60	283.0	5.00	40.00
3	1	1.90	500.000	_ _ _._	4.09	284.0	5.00	45.00
4	1	1.90	500.000	_ _ _._	3.68	285.0	5.00	50.00

Figure 2 – Four Separate Processes with a Single Hold Tube Section and Fo

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
1	1	1.26	160.00	165.0	0.46		0.68	
1	2	1.95	425.00	_ _ _._	2.94	283.0	4.32	50.00
1							5.00	

Figure 3 - Single Process with Multiple Hold Tube Sections with Different Diameters/Lengths

3. Column 3. Inside Diameter of Hold Tube Section

List the internal diameter of the hold tube in inches using one digit before the decimal point and three digits after the decimal point. When the diameter is less than an inch, enter zero as the digit before the decimal point. If the internal diameter varies along the length of the hold tube, list the internal diameter for each section as illustrated in Figure 3.

4. Column 4. Hold Tube Section Length

List the hold tube length in inches using a maximum of four digits before the decimal point and three digits after the decimal point. If the internal diameter varies along the length of the hold tube, list the hold tube length for each section of the hold tube as illustrated in Figure 3.

5. Column 5. Initial Temperature

Fill out this column only if you selected "Direct Heating" in section E.1.b.i and "Before the heater" in section E.1.b.iii of the form. Enter the initial temperature at the beginning of the first heater in the product flow stream before the hold tube. If the internal diameter varies along the length of the hold tube, enter the initial temperature for the first section only, as illustrated in Figure 3. Enter this temperature in degrees Fahrenheit using a maximum of three digits before the decimal point and one digit after the decimal point. Otherwise, continue to column 6 on the form.

6. Column 6. Process Time

Enter the duration of the process time for each hold tube section in the scheduled process in seconds and fractions of a second using a maximum of three digits before the decimal point and three digits after the decimal point. If the duration is a whole second, enter the number of seconds and three zeros for the decimal portion. If the internal diameter varies along the length of the hold tube, enter the process time for each hold tube section, as illustrated in Figure 3.

Examples of how to enter process time:

- If the process time is 15 seconds and 0 fractions of a second, enter 15.000
- If the process time is 15 seconds and a quarter of a second, enter 15.250
- If the process time is 1 minute and 15 seconds, enter 75.000

7. Temperature (at exit of final hold tube section)

Enter the temperature at the exit of the hold tube in degrees Fahrenheit using a maximum of three digits before the decimal point and one digit after the decimal point. If the internal diameter varies along the length of the hold tube, do not enter the temperature at the exit of each hold tube section; instead, only enter the temperature at the exit of the final hold tube in the final section as illustrated in Figure 3.

8. Column 8. Fo (F18/250)

Enter the number of minutes that the process requires to achieve commercial sterility using a z value of 18 degrees Fahrenheit and a reference temperature of 250 degrees Fahrenheit. This is the Fo value. If the internal diameter varies along the length of the hold tube, enter the Fo value for each hold tube section. After you have entered Fo values for each hold tube section, add the values together and in a new row, enter in column 1 the same process number for that process and in column 8 the total accumulated Fo from all the hold tubes.. Refer to Figure 3 for an example. For each Fo value, enter the number of minutes using a maximum of two digits before the decimal point and two digits after the decimal point.

Examples of how to enter the Fo:

- 6.00
- 6.35

9. Column 9. Maximum Product Flow Rate

Enter the maximum product flow rate in gallons per minute at the hold tube outlet using a maximum of two digits before the decimal point and two digits after the decimal point. If the internal diameter varies along the length of the hold tube, enter the maximum product flow rate in the final section, as illustrated in Figure 3.

K. Step 10 – Section I. Additional Information (Optional)

Under this section of the form, you may provide optional attachments. Select this choice and identify the document name in the space provided.

1. Comments:

Enter any additional information you consider pertinent to the product and/or the scheduled process critical factor(s). Comments are optional unless you report multiple forms of the product, multiple packing mediums, or multiple product variations, in which case comments may be required in some circumstances as discussed under section II.A (General Information) in this document.

If you report multiple forms of a product (e.g., diced, chunks, cut, fillet), multiple packing mediums, or multiple products with minor formulation changes on a single form, the heat transfer rates may differ for each product variation. In such cases, the process for the slowest heating formulation of the product or its packing medium must be filed and you should use the comment box section to specify which formulation packing medium heats the slowest.

If you consider any additional information pertinent to the product and/or the scheduled process critical factor(s), enter that information in the comment box and/or attach one or more documents containing the additional information as discussed in section II.I.

2. Full Name, Signature, Establishment Name, and Date

Print the first and last name of the person authorized to represent the facility, as well as the FCE facility name, state (for US) or province (for foreign countries), and country. The person authorized to represent the facility must sign and date the form and provide the authorized person's telephone number.

III. How to Contact FDA or Obtain Help

You may contact us:

- By email at LACF@fda.hhs.gov;
- By telephone at 240-402-2411; and

- By mail at the address immediately below.

Food and Drug Administration
LACF Registration Coordinator (HFS-303)
Center for Food Safety and Applied Nutrition
5100 Paint Branch Parkway
College Park, Maryland 20740-3835

IV. References

1. Guidance for Industry: Submitting Form FDA 2541 (Food Canning Establishment Registration) and Forms FDA 2541d, FDA 2541e, FDA 2541f, and FDA 2541g (Food Process Filing Forms) to FDA in Electronic or Paper Format. Accessible at http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm309376.htm

2. Guidelines for Microbiological Validation of the Sterilization of Aseptic Filling Machines and Packages, including Containers and Closures. Accessible at http://www.iftps.org/protocols.html

3. Metric (mm) to English (inches and sixteenths) Container Dimension Conversion Chart. Accessible at http://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/AcidifiedLACFRegistration/ucm125836.htm

4. Supplemental Submission Information Table Format Example. Accessible at http://www.fda.gov/downloads/Food/GuidanceRegulation/FoodFacilityRegistration/AcidifiedLACFRegistration/UCM417293.pdf

5. LACF/AF Precursor Questions. Accessible at http://www.fda.gov/downloads/Food/GuidanceRegulation/FoodFacilityRegistration/AcidifiedLACFRegistration/UCM417292.pdf

IV. Appendix

A. Container Types and Shapes

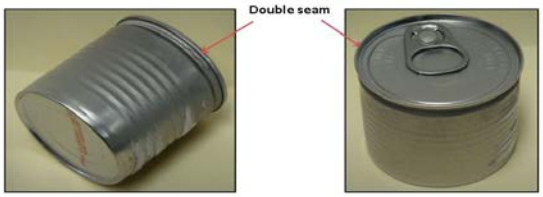

Figure 4 – Cylindrical Shape 2-Piece Aluminum Containers Depicting Double Seams

Figure 5 – Low Profile Rectangular Shape 2-Piece Aluminum Containers

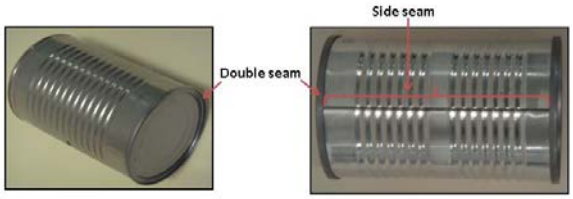

Figure 6 – Cylindrical Shape 3-Piece Steel Containers with a Double Seam and Side Seam

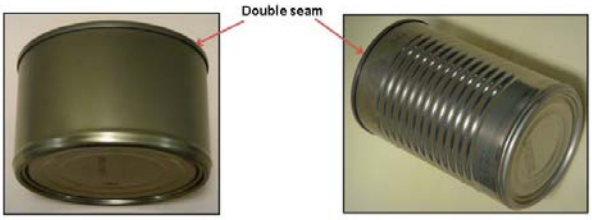

Figure 7 – Cylindrical Shape 2-Piece Steel Containers with a Double Seam

Figure 8 – Flexible Pouch

Figure 9 – Glass Containers

Figure 10 – Semi Rigid Body, Oval Shape Containers with Heat Seal

Figure 11 – Semi Rigid Body, Rectangle Shape Containers

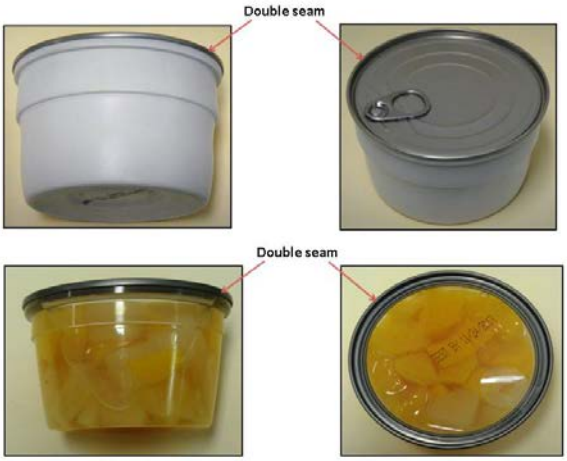

Figure 12 – Semi Rigid Body with an Aluminum Double Seam

Figure 13 – Semi Rigid Body, Cylinder Shape Containers with Induction Weld Seal.

Figure 14 – Semi Rigid Body with Heat Seal

B. Container Dimension Measurements

Container dimension measurements should always be measured from the outside edge of the container. Below, we list different types of materials and descriptions of how to properly measure the dimensions of the container.

1. Cylindrical Measurement

Measure the diameter from the outside of the double seam on the container. Measure the height from the top of the double seam to the opposing double seam top. If the can is a two piece can, measure from the top of the double seam to the furthest point on the other end. For glass bottles or unusually shaped cylindrical containers, always measure the widest part of the container.

For heat-sealed, semi-rigid containers, do not measure the sealing flange as part of the container dimensions. Only measure from the inner edge of the flange where the seal edge meets the chamber holding the food.

When measuring cylindrical shaped containers, list diameter x height (e.g., 0211 x 0400 for a 2 11/16 inch x 4 inch container).

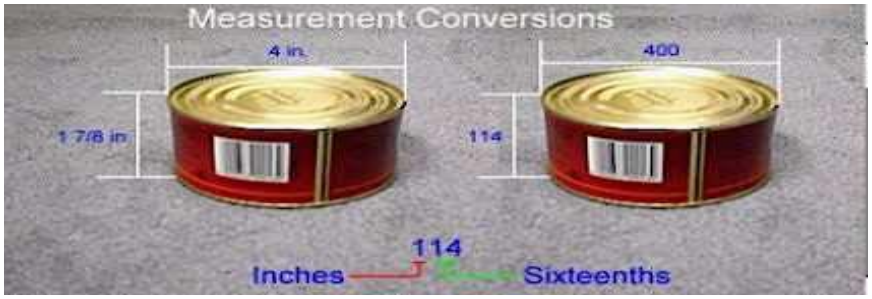

Figure 15 – Measurement of a Cylindrical Shape Container.

When measuring unusually shaped cylindrical containers, always measure the widest part of the container.

Figure 16 – Measurement of an Unusual Shape Cylindrical Container.

2. Oval Shape Measurement

When measuring unusually shaped oval containers, always measure the widest part of the container.

Figure 17 – Measurement of an Oval Shape Container

Figure 18 – Measurement of Outer Edges of Container

3. Rectangular Shape, Rectangular Tray and Low Profile Measurement

For all rectangular containers (including trays), list length (longest dimension) x width (second longest dimension) x height; for example, list 0405 x 0301 x 0014 for a container that is 4 5/16 inches long, 3 1/16 inches wide, and 14/16 of an inch.

For a rectangular can, measure the length and width from outside of the double seam. When measuring the height of the container, measure from the top of the double seam to the furthest point on the bottom.

For a rectangular pouch, measure from the inner edge of the seams for the length and width. For the height, measure the thickness at the thickest point.

For paper board rectangular containers, measure the length, width, and height from the outside edge of the container.

4. Rectangular Shape Measurement

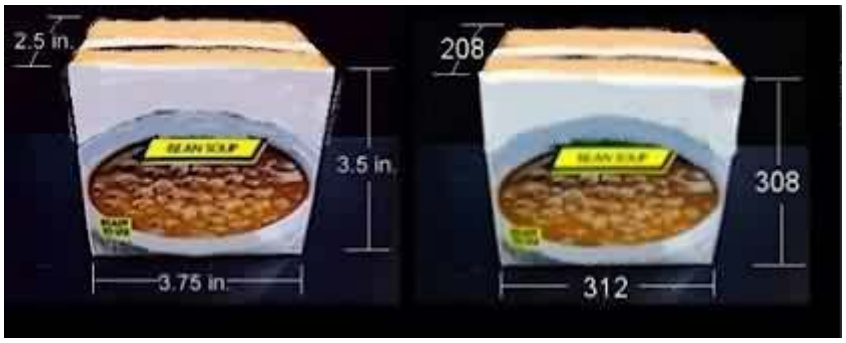

Figure 19 – Measurement of a Rectangular Shape Container

5. Rectangular Tray Measurement

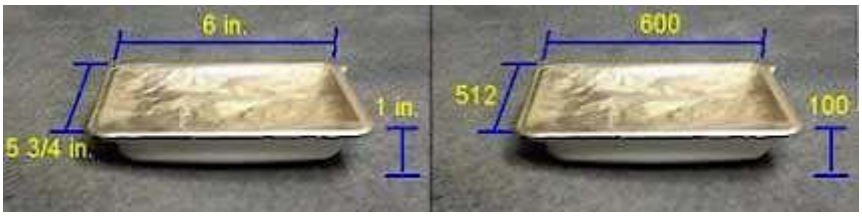

Figure 20 – Measurement of a Rectangular Tray Shape Container

6. Low Profile Measurement

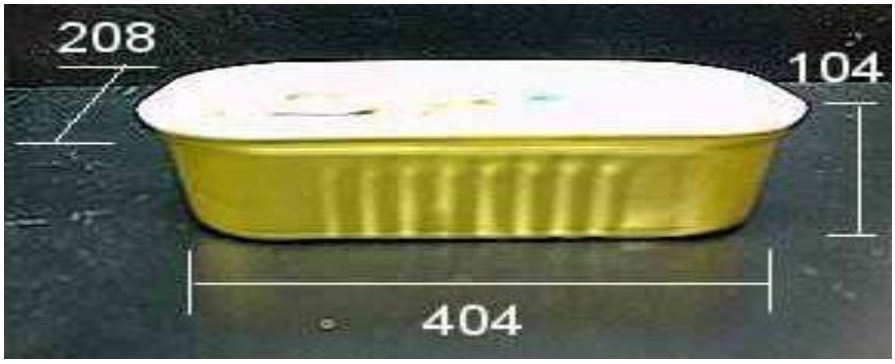

Figure 21 – Measurement of a Low Profile Container

C. Supplemental Submission Attachment for Form FDA 2541g

1. Food Canning Establishment (FCE) Number

Provide the FCE number as described in section II.B.1 in these instructions.

2. Supplemental Submission Identifier (SUP SID)

Aseptic processing involves up to three separate systems: a product sterilization system, an optional aseptic surge tank system, and a package sterilization system. The "Supplemental Submission Attachment for Form FDA 2541g" ("Supplemental Submission") that you attach to Form FDA 2541g is designed for you to provide detailed information about your product and package sterilization systems, and about your aseptic surge tank system if you use one. For each attachment in the space provided, enter the document name for each attachment.

Each Supplemental Submission is identified by a unique identifier, called a "SUP SID." The SUP SID is a unique number associated with each Supplemental Submission for a facility. You assign the SUP SID. The SUP SID identifies a specific attachment for a packaging system and is attached as a document to a submission which is the combination of the FCE number and Submission Identifier as described in section II.B.1 and II.B.2 of these instructions.

The SUP SID identifier should be a combination of:

- (1) The date (i.e., year, month, and day of the month) that identifies the date you sent us the Supplemental Submission; and
- (2) A sequence number that would distinguish multiple Supplemental Submissions, each associated with a different product and package aseptic system, created on the same date. The sequence number starts with 001 and continues (002, 003, 004) for as long as necessary to uniquely identify each supplemental submission created on the same date. Each product and packaging aseptic system will have a unique number.

The SUP SID identifier should use the following format:

YYYY-MM-DD-SSS

Where:

YYYY represents the calendar year (e.g., 2013, 2014)

MM represents the month (e.g., 02 for February, 10 for October)

DD represents the day of the month (e.g., 02, 19, 30)

SSS represents the assigned sequence number (e.g., 001, 002, 003).

Examples of SUP SID identifiers include:

2013-02-22-001: The first Supplemental Submission created on February 22, 2013

2013-02-22-002: The second Supplemental Submission created on February 22, 2013

2013-02-22-003: The third Supplemental Submission created on February 22, 2013

You may only attach the same Supplemental Submission for more than one Form FDA 2541g if the product described in the Form FDA 2541g all use the same product and package sterilization system, as well as the same aseptic surge tank if applicable.

3. General Information about the Supplemental Submission

We recommend that you organize information in your Supplemental Submission in tables to the extent practical. You may find it useful to use a computer spreadsheet program or a word processing program that helps in creating tables. Refer to Ref. 4 in this document for an example of a table prepared using spreadsheet software.[5]

Unless you or the manufacturer of your package sterilization system has previously submitted a process validation study concerning your package sterilization system to FDA, you must provide a process validation study along with your Supplemental Submission. The process validation study must provide a detailed description of the equipment, package, and the biological challenge study for the package sterilization system. In addition, when a surge tank is used, the process validation study must include a temperature distribution study for the surge tank. When validating an aseptic package sterilization system, we recommend that you follow generally available recommendations and methods such as those provided by the Institute for Thermal Processing Specialists (Ref. 2). The information contained in your process validation study in Metric or English units of measurement, and temperature Fahrenheit. We will review the process validation study for a new aseptic package sterilization system and if we have questions, we will contact you.

We also recommend that equipment manufacturers, process establishments, and Process Authorities meet with us during development and validation of an aseptic package sterilization system (see Section III of this document, entitled “How to Contact FDA or Obtain Help”).

[5] The information in Ref. 4 has been organized into three categories: 1) information about the FCE and SUP SID numbers; 2) information about critical factors; and 3) signature information. Within the second category (i.e. information about critical factors), information is separately provided regarding the product sterilizer, the aseptic holding tank, and the packaging sterilizer. The information regarding the packaging sterilizer is separately divided to address specifications to achieve commercial sterility and specifications to maintain commercial sterility. This reference is provided as an example only. You are not required to format your information in this way.

Although your process validation study may be reported in Metric units, you should report the supplemental information described below regarding critical factors for the aseptic sterilization system in English units. For help in converting Metric units to English units, refer to Ref. 3 which provides a link to conversion charts.

4. Critical Factors for the Aseptic Sterilization System

Your Supplemental Submission must include information about critical factors associated with the aseptic sterilization system, including information about critical factors associated with the product sterilization system, the aseptic surge tank if you use one, and the package sterilization system. (Note that this is distinct from Section F of Form FDA 2541g, in which you provide information about critical factors for the product.) Under 21 CFR 113.3(f), critical factors are any property, characteristic, condition, aspect, or other parameter, variation of which may affect the scheduled process and the attainment of commercial sterility. Part 113 requires that the processing of low-acid canned foods be done in a manner that ensures that commercial sterility is achieved. Your Supplemental Submission must identify any critical factors, controls, or other information necessary to achieve and maintain commercial sterility that are specified by the process source for your aseptic sterilization system.

As examples of common critical factors that may apply to product sterilization systems, aseptic surge tanks, and package sterilization systems, we've created the following list. (Note, however, that the list is not intended to be exhaustive, and your product sterilization system, aseptic surge tank, or package sterilization systems may not involve all of these critical factors, or might involve additional critical factors):

- Sterilizing medium
- Temperature
- Time (e.g. exposure time, residence time)
- Pressure (e.g., air pressure, culinary steam supply pressure)
- Sterilizing medium concentration
- Flow rate of sterilizing medium (e.g., high pressure hot water)
- Phase characteristics of sterilizing medium (e.g., vapor, liquid, spray, fog, or mist)
- Relative humidity (e.g., dew point)
- Surface tension
- Elevation
- Removal of sterilizing medium (e.g., removal of chemical residue or condensate)
- Package splicing
- Absence of a container or closure
- Radiation intensity and dose
- Piping and ductwork design
- Presence/absence of optional components or devices such as head space injection
- Event sequence (i.e., activation timing of valve actuators, pumps, heating elements)
- Transition to next state of operation
- Effect of concurrent practices (e.g., product path sterilization concurrent with aseptic zone sterilization)

- Interruptions, short stops and jams

In addition to identifying each critical factor that must be controlled such that the product sterilization system, the aseptic surge tank, or the package sterilization system achieves and maintains commercial sterility, you must also provide all information necessary to assess the control of each specified critical factor. Below, we list examples of such information:

- Threshold Value – Identify the critical value that will establish and/or maintain sterility.
- Limit – Identify the limit, either maximum or minimum, that you set for each critical factor. The critical limit is set such that if the value is not met, the safety of the product may be questionable.
- Control/Pen and Ink Diagram (P&ID) Tag – Identify how this factor is controlled and the labeling number or tag of the instrument used to control each critical factor (e.g., manual, Programmable Logic Computer (PLC) and/or Temperature at Location 1 (T1), Pressure at Location 7 (P7)).
- Corrective Action –For each critical factor, describe the procedure(s) that are used when monitoring indicates that the critical limit has not been met.
- Record – Identify the method of recordkeeping used to document that critical factors were controlled (e.g., strip chart, operator log, or electronic record).
- Frequency – Identify the frequency of generating records documenting the control of critical factors (e.g., 15 minute intervals, continuous monitoring, etc).

Sections 4.A. (Product Sterilization System), 4.B. (Aseptic Surge Tank), and 4.C. (Package Sterilization System) describe specific information that you should provide in your Supplemental Submission.

4.A. Product Sterilization System

Specify the Manufacturer's name and model number for the Product Sterilization System. Provide information for each of the critical factors described below, as well as any other critical factors identified by your process source.

Submit information in English units of measurement and temperature in degrees Fahrenheit. For help in converting Metric measurements to English measurements and temperature in degrees Celsius to temperature in degrees Fahrenheit, refer to Ref. 3, which provides a link to conversion charts.

4.A.1. Sterilizing Medium

Specify the sterilizing medium used to achieve commercial sterility in the product sterilization system and all product contact surfaces downstream from the holding tube in the system (e.g., water, steam, hydrogen peroxide, etc.). Refer to Figure 22 or Ref. 4 in this document for examples of how to present this information. If the sterilizing medium is a chemical, specify the threshold value as the minimum concentration of the chemical.

4.A.1.1. Minimum Sterilizing Temperature

Specify the minimum sterilizing temperature used to achieve commercial sterility in the product sterilization system and all product contact surfaces downstream from the holding tube in the sterilization system. Express the temperature in degrees Fahrenheit using a maximum of three digits before the decimal point and one digit after the decimal point.

4.A.1.2. Minimum Time

Specify the minimum time (in minutes) that the sterilizing medium must be recirculated through the product sterilization system to achieve a condition of commercial sterility.

4.A.1.3. Minimum Back Pressure

Specify the minimum back pressure required at the specific location in the product sterilization system to prevent flashing of water to steam (and hence, a reduced holding time in the holding tube). Specify minimum back pressure in pounds per square inch gauge (psig) and location of measurement.

4.A.1.4. Other

Specify any additional critical factors under “Other.” Report any temperatures in degrees Fahrenheit.

A. PRODUCT STERILIZATION SYSTEM: _____

ID Number	Description of Critical Factor	Threshold Value	Unit of Measure	Limit	Control/P&ID Tag	Corrective Action	Record	Frequency
1	Sterilizing Medium - Steam	Saturated						
1.1	Minimum Sterilizing Temperature	250	[°F]	min	T1	Product Sterilizer has to be repeated	Strip Chart	Continuous
1.2	Minimum Time	30	[min]	min	PLC		Strip Chart	Continuous
1.3	Minimum Back Pressure	59	[psig]	min	P1		Strip Chart	Continuous
1.4	Other (add additional critical factors and associated details as necessary)							

Figure 22 – Example of SUP SID information for the Product Sterilization System in a Spreadsheet Format

4.B. Aseptic Surge Tank

Surge tanks are sometimes used in aseptic systems to hold sterile product before packaging, especially for systems in which the flow rate of a product sterilization system is much faster than the filling rate of a given packaging unit. If you use an aseptic surge tank, specify the Manufacturer’s name and model number for the Aseptic Surge Tank. Provide information for each of the critical factors described below and any other critical factors identified by your process source.

Submit information in English units of measurement and temperature in degrees Fahrenheit.

4.B.1.1. Minimum Sterilizing Temperature

Specify the minimum sterilizing temperature used to achieve commercial sterility in the aseptic surge tank and all product contact surfaces downstream from the surge tank.

Express the temperature in degrees Fahrenheit using a maximum of three digits before the decimal point and one digit after the decimal point.

4.B.1.2. Minimum Time

Specify the minimum time (in minutes) that the sterilizing medium must be recirculated through the surge tank to achieve a condition of commercial sterility.

4.B.1.3. Sterile overpressure to maintain sterility

Sterile overpressure is the amount of positive pressure that must be maintained in the holding tank at all times to consider the surge tank sterile. Specify the sterile overpressure to maintain sterility in pounds per square inch gauge (psig). Specify any critical factors necessary to maintain sterile overpressure (e.g., incineration temperature of air, replacement and/or sterilization frequency for bacteriological filters).

4.B.1.4. Other

Identify any additional critical factors under "Other." Report any temperatures in degrees Fahrenheit.

4.C. Package Sterilization System

Specify the Manufacturer's name and model number for the Package Sterilization System. Provide information for each of the critical factors described below and any other critical factors identified by your process source.

Submit information in English units of measurement and temperature in degrees Fahrenheit.

- The critical factors in items C.1 through C.5 are used to *achieve* commercial sterility of the specified equipment and package, including the container and closure.
- The critical factors in items C.6 through C.8 are used to *maintain* commercial sterility of the specified equipment and package, including the container and closure.

a. Critical factors used to achieve commercial sterility

4.C.1 Sterilizing Filters that Will Be Used with Compressed Air

Sterile filters are used when compressed air is added to the aseptic system so that the compressed air is sterile when it enters the aseptic system. Specify the sterilizing medium, temperature, time, and any other factors necessary to sterilize the filter. If the sterilizing medium is a chemical, specify the threshold value as the minimum concentration of the chemical. Specify the maximum amount of time between sterilization cycles.

4.C.2. Aseptic Chamber Pre-Heating

If preheating the aseptic chamber is critical to achieving sterility (because it prevents condensation on the equipment), specify the heating medium, temperature and time necessary to heat the aseptic chamber before sterilization. If the heating medium is a chemical, specify the threshold value as the minimum concentration of the chemical.

4.C.3. Aseptic Chamber Sterilization

Specify the critical factors (such as sterilizing medium, temperature, time for circulating medium, sterile air overpressure, etc.) necessary to bring the aseptic chamber to a condition of commercial sterility before the start of the filling operation. If the sterilizing medium is a chemical, specify the threshold value as the minimum concentration of the chemical.

4.C.4. Container and Closure Sterilization

You must attain a condition of commercial sterility for both the containers and the closures before filling the commercially sterile product into the containers. Specify the critical factors (such as sterilizing medium, temperature, minimum exposure time or maximum conveyor/film speed, etc.) necessary to bring the container and closures to commercial sterility before filling the commercially sterile product into the containers. If the sterilizing medium is a chemical, specify the threshold value as the minimum concentration of the chemical. If the containers receive a different sterilization process than the closures, specify one set of critical factors for the containers and another set of critical factors for the closures.

4.C.5. Other

Specify any additional critical factors used to achieve commercial sterility under "Other." Report any temperatures in degrees Fahrenheit.

b. Critical factors used to maintain commercial sterility

4.C.6. Aseptic Chamber Sterilization

Specify the minimum amount of sterile overpressure used in the aseptic chamber to maintain the sterility of the aseptic environment in pounds per square inch gauge (psig). Refer to Figure 23 or Ref. 4 in this document for examples of how to represent this information.

B. ASEPTIC SURGE TANK: _____

ID Number	Description of Critical Factor	Threshold Value	Unit of Measure	Limit	Control/P&ID Tag	Corrective Action	Record	Frequency
1	Sterilizing Medium - Steam	Saturated						
1.1	Minimum Sterilizing Temperature	250	[°F]	min	T2	Surge tank must be resterilized	Strip Chart	Continuous
1.2	Minimum Time	30	[min]	min	PLC		Strip Chart	Continuous
1.3	Sterile overpressure to maintain sterility	3	[psig]	min	P2		Strip Chart	Continuous
1.4	Other (add additional critical factors and associated details as necessary)							

Figure 23 – SUP SID information for Aseptic Chamber Sterilization in a Spreadsheet Format

4.C.7. Containers and Closures

Specify the critical factors necessary to maintain the sterility of the containers and closures (such as sterilizing medium, temperature, minimum exposure time or maximum conveyor/film speed, etc.). If the sterilizing medium is a chemical, specify the threshold value as the minimum concentration of the chemical. If the container receives a different sterilization process than the closure, specify one set of critical factors for the containers and another set of critical factors for the closures.

4.C.8. Other

Specify any additional critical factors used to maintain commercial sterility under "Other." Report any temperatures in degrees Fahrenheit.

5. Signature

At the bottom of each document you submit as part of your Supplemental Submission, print the first and last name of the person authorized to represent the facility, as well as that person's telephone number. The person authorized to represent the facility must sign and date the Supplemental Submission document.

D. Abbreviations

Abbreviation	Full Term
AF	Acidified Food
AR	Authorized Representative
ECP	Establishment Contact Person
FCE	Food Canning Establishment
FFR	Food Facility Registration
FIS	FDA Industry System
FURLS	FDA Unified Registration and Listing Systems
LACF	Low-Acid Canned Foods
ROAR	Read Only Authorized Representative
SID	Submission Identifier
SUPER AR	Super Authorized Representative