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FDA Form 2541c

IFTPS

Institute For Thermal Processing Specialists

26th Annual Conference & General Meeting

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Background for 2541c

1. FDA Form 2541c is used for filing processes that use aseptic processing and packaging systems.
2. The form is only used for LACF products under 21 CFR 108.35.
3. It is required that each block on the form be completed in English.
4. Unless otherwise indicated, all blocks on the form must be completed.

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2541c

DEPARTMENT OF HEALTH AND HUMAN SERVICES ■ Public Health Service ■ 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: 9/30/02

FDA USE ONLY

DATE RECEIVED BY FDA

1. FCE _ _ _ _ _

2. ESTABLISHMENT NAME

ADDRESS *(No. and Street)*

CITY | STATE

ZIP CODE | COUNTRY

3. SID 20YYYY-MM-DD/SSS

4. ☐ NEW ☐ CANCELS ☐ REPLACES YYYY-MM-DD/SSS

5. ☐ SCHEDULED ☐ ALTERNATE FOR YYYY-MM-DD/SSS

6. SUP SID 20YYYY-MM-DD/SSS

7. PRODUCT NAME, FORM OR STYLE, AND PACKING MEDIUM

8. NAMES OF STERILIZING SYSTEMS

a. Product [1]

b. Packaging

9. PROCESS ORIGIN

No.	Source for 8.a. and 8.b.	Date *(mm/yyyy)*
a.		
b.		

10. CONTAINER TYPE *(Check one)*

a. ☐ Tinplate or Steel Can b. ☐ Aluminum Can c. ☐ Glass d. ☐ Other *(Specify below and in Item 22 if necessary)*

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	Method Name	Viscosity Characteristic			
0.	.	.	.	.				N ☐ P ☐ D ☐	.	.	.

17. OTHER CRITICAL CONTROL FACTORS *(Check all that apply)*

61 ☐ Percent Solids
62 ☐ Ratio of Solids to Liquids
63 ☐ Syrup Strength
68 ☐ Method of Preparation
70 ☐ Formulation
71 ☐ Rehydration *(specify method in 22)*
72 ☐ Particulates *(specify maximum size in 22)*
73 ☐ Other *(specify in 22)*

No.	18. CONTAINER DIMENSIONS (Inches and Sixteenths)			19. SCHEDULED PROCESS					20. MAXIMUM FOOD FLOW RATE (gal / min)	21. THRUPUT (containers / minute)
	Diameter or Length	Height or Width	Height	Minimum Initial [4] Temp (°F)	Time (sec)	Temp (°F)	Least Sterilizing Value (°F) [5]	Flow Correction Factor		
1					.		.	.		
2					.		.	.		
3					.		.	.		
4					.		.	.		
5					.		.	.		
6					.		.	.		

FOOTNOTES

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.

22. COMMENTS

AUTHORIZED COMPANY REPRESENTATIVE

NAME *(Type or Print)* | TITLE

SIGNATURE | DATE | PHONE NO.

FORM FDA 2541c (1/99) PREVIOUS EDITION IS OBSOLETE

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Instructions for 2541c

Item 1 - FCE (Food Canning Establishment) #

1. A FCE is a registration number given to each food plant, which is entered into the FDA computer system and allows the Agency immediate access to a food manufacturers filings.
2. If the plant is already registered, enter the five (5) digit number.
3. If the food plant is being registered concurrently with the filing submission, leave the space blank and the FDA will complete it.
4. When the FCE number is obtained from the FDA record the number on copies of all filing forms.

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Item 2 – Establishment Name and Address

2.	ESTABLISHMENT NAME	
	ADDRESS *(No. and Street)*	
	CITY	STATE
	ZIP CODE	COUNTRY

1. The purpose of this is to identify the physical location of the plant and upon inspection it can be verified that the plant actually exists.

Domestic

2. The manufacturer's name and address must be the same as the one submitted to the FDA for the FCE #.

3. The actual manufacturing site for the filed products should be provided as the plant address.

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Item 2 – Name and Address continued

Foreign

4. **In the state designation, enter the name or abbreviation of the province or subdivision of your country.**
5. **Enter the appropriate postal code established by the country's postal department in the zip code section.**
6. **In the country designation, enter the name of the country in which the manufacturing plant is located.**

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Item 3 – Submission Identifier (SID)

1. The SID is a unique number assigned to each filing and entered into the FDA computers allowing traceability of all filings when used with the plant FCE number.
2. The first entry is the four digit year (i.e. 2007).
3. The second entry is the month represented as two digits in which the form is completed (i.e. 02 for February).
4. The day of submission is the next item and is entered as two digits in which the form is completed (i.e. 05 for the fifth day)
5. The last item is the sequence of the filing within the date (i.e. 001, 002, etc).

2007-02-05/001 for the first filing of that specific day.
2007-02-05/002 for the second of that specific day.

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Item 4 – New, Replacement or Cancellation

1. This describes the type of filing being submitted for the product.
2. If the product has no previous filings for the product in the container sizes listed “NEW” is selected.
3. If the previously submitted filing is being cancelled, then select “CANCEL”. The SID for the filing which is being cancelled must be supplied in the space allotted. To ensure the correct process filing is cancelled, the food name should be entered under Item 7 using the appropriate instructions.
4. If the product has been previously filed and this is replacing that filing select “REPLACES”. The SID for the filing which is being replaced must be supplied in the space allotted.

Instructions for 2541c

Item 5 – Scheduled or Alternate

1. Scheduled or alternate processes notify the FDA when there is more than a single process for a product.
2. If the process being filed is the one normally used under normal conditions, then “SCHEDULED” should be selected.
3. If the facility “Regularly” uses another process for a process which has been filed separately then select “ALTERNATE FOR”. The SID must be provided for the filed scheduled process. The alternate process should be reported ONLY IF USED REGULARLY.

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Item 6 – Required Supplemental Information for Aseptic Packaging Systems (SUP SID)

1. A SUP SID is required for each aseptic packaging system that is filed to give the FDA all critical information necessary to safely operate the equipment.

2. The supplemental information is given a unique SID number which the FDA enters into the computers and uses to track adherence to the regulations for a specific system.

3. The procedure used to assign a SID is the same as provided under Item 3, 2-4.

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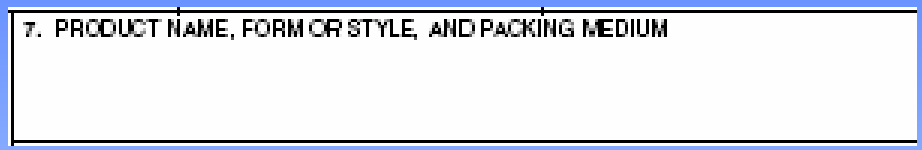
Item 7 – Food Product Name, Form or Style, and Packaging Medium.



1. This is used to identify the product being processed on the aseptic system.
2. The food product name, form or style must be recorded on the form in that order (i.e. whole milk, chocolate pudding, etc…).
3. After the name, form or style is recorded then the packing medium must be entered (i.e. particulate).

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4. If the product has different forms or styles, a separate 2541c must be used for each if it has a different scheduled process (i.e. whole milk, skim milk, etc.) or if the characteristics of the food affects the heat transfer or microbial heat resistance a different 2541c must be used.

5. Product forms or styles which have the same scheduled process should be included in parentheses after the product name.

6. The English name as well as the non-English name as given on the container label should be included for foreign firms.

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Item 8 – Names of the Sterilizing Systems

8. NAMES OF STERILIZING SYSTEMS	
	a. Product[1]
	b. Packaging

1. The purpose of this block is to define the make and model of the aseptic processing system. In Part a and b, the names of the product sterilizer and packaging system must be provided. In addition to the names, the manufacturers' model numbers have to be supplied. This allows the FDA to confirm the equipment being used on site during an audit.

2. Limit the name to 30 characters if possible. Abbreviations can be used, but must be clear as to the meaning (i.e. Cherry Burrell: Swept Surface Ht. Ex, DuPont DA2000 Pouch Filler).

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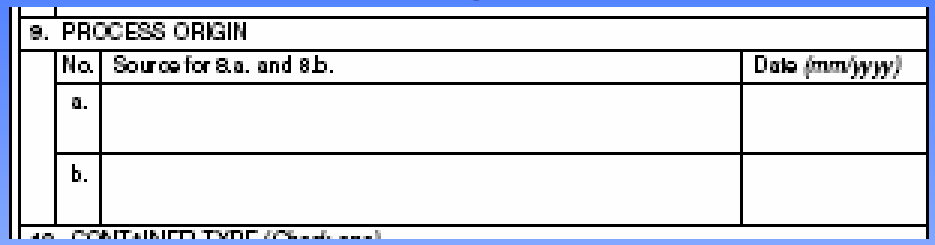
Item 9 – Process Origin



9. PROCESS ORIGIN		
No.	Source for 8.a. and 8.b.	Date (mm/yyyy)
a.		
b.		

1. The process origin information provides the name of the Process Authority (PA) who performed the scientific studies to establish the scheduled process for the processor and packaging system.

2. Item 9a - Enter the name for the Process Authority for the product. Follow this with the date for the process origin using a numerical (two digit) month and (four digit) year format.

3. Item 9b - Enter the name for the Process Authority for the packaging system. Follow this with the date for the process origin using a numerical (two digit) month and (four digit) year format.

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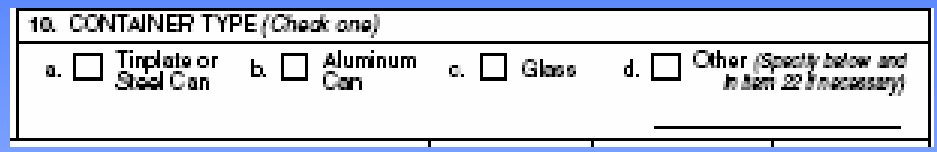
Item 10 – Container Type


10. CONTAINER TYPE *(Check one)*

a. ☐ Tinplate or Steel Can b. ☐ Aluminum Can c. ☐ Glass d. ☐ Other *(Specify below and in Item 22 if necessary)*

1. The purpose of this section is to describe the type of aseptic container used to package the commercially sterile product.

2. A separate filing form must be used for each different type of container, even if all other information is identical. The only exception is tinplate/steel and aluminum cans which can use the same 2541c form.

3. If *Other* is selected, provide a description of the container type in the comments section in Item 22.

   For Example: Pouch (polyethylene/alum. Foil laminate); Semi-Rigid containers (cups. Bottles, etc)

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Item 11 – Maximum Water Activity

11. MAXIMUM WATER ACTIVITY [2]	12. pH		13. MAXIMUM CONSISTENCY OR VISCOSITY IN CENTIPOISES OR APPROPRIATE UNITS					
	Normal	Max. [3]	Value at 77 ±2°F	Value at Other Temp	Other Temp (°F)	Units	Method Name	Viscosity Characteristic
0.	.	.	.	.				N ☐ P ☐ D ☐

1. The purpose of this block is to specify if water activity is critical to achieving the scheduled process. If it is critical, enter the value to the nearest hundredth (i.e. 0.88).
2. If the water activity is not critical then enter N/A.
3. If water activity is critical to the process and the block is completed then water activity must be <u>monitored</u>, <u>controlled</u> and <u>recorded</u> during processing of the product.
4. If water activity controls *C. botulinum*, the Agency asks the firms to file using 2541a.

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Instructions for 2541c

Item 12 – pH

11. MAXIMUM WATER ACTIVITY [2]	12. pH		13. MAXIMUM CONSISTENCY OR VISCOSITY IN CENTIPOISES OR APPROPRIATE UNITS					
	Normal	Max. [3]	Value at 77 ±2°F	Value at Other Temp	Other Temp (°F)	Units	Method Name	Viscosity Characteristic
0.	.	.	.	.				N ☐ P ☐ D ☐

1. There are two purposes for this block, the first is to confirm the product is low acid and must be filed with the FDA. The second is to determine if pH is critical in achieving the scheduled process.
2. The normal product pH before processing is entered to the nearest tenth (i.e. 6.2).
3. If pH is listed as a critical factor by the PA, enter the maximum equilibrium pH (upper limit) of the finished product after acidification.
4. The pH must be measured within 24 hours after processing of the product.

Instructions for 2541c

Item 13 – Maximum Consistency or Viscosity

11. MAXIMUM WATER ACTIVITY [2]	12. pH		13. MAXIMUM CONSISTENCY OR VISCOSITY IN CENTIPOISES OR APPROPRIATE UNITS					
	Normal	Max. [3]	Value at 77 ±2°F	Value at Other Temp	Other Temp (°F)	Units	Method Name	Viscosity Characteristic
0.	.	.	.	.				N ☐ P ☐ D ☐

1. In aseptic processing, viscosity is important in determining the type of process which should be applied to a continuous flow product in a pipe (i.e. laminar or turbulent).
2. The consistency or viscosity of a product is entered only if determined to be critical to achieving the scheduled process as determined by the process authority designated in Item 9.
3. If consistency or viscosity are not applicable, enter N/A.
4. If consistency or viscosity is applicable, enter the values specified in Item 13.

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Product Viscosity Characteristics

1. The 2541c deals with three types of fluid viscosity in determining the flow characteristics. If viscosity is determined to be critical then the product characteristic has to be determined and selected as part of the filing. The three main types of viscosity for food products are:

   N – Newtonian. Viscosity remains constant with changes in shear rate. P – Pseudoplastic. Viscosity decreases as shear increases and D – Dilitant. Viscosity increases as shear increases.

2. Product viscosity characteristics can be found in scientific literature, handbooks or by direct measurement.

3. If direct measurement is used, product viscosity is determined using three (3) rates of shear at the same temperature.

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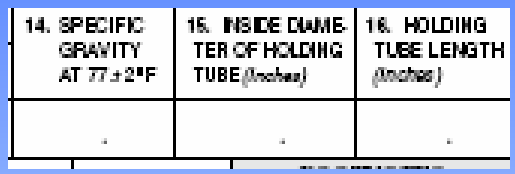
Items 14-16: Specific Gravity, Hold Tube ID, and Hold Tube Length



14. SPECIFIC GRAVITY AT 77 ± 2°F	15. INSIDE DIAMETER OF HOLDING TUBE (Inches)	16. HOLDING TUBE LENGTH (Inches)

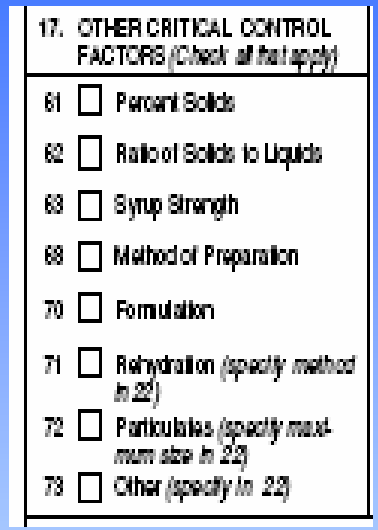
1. **Specific gravity of foods is an important factor used in determination of the Reynolds Number which is important in determining flow characteristics of the product (i.e. turbulent or laminar). The value is entered to the nearest thousandth (i.e. 1.019).**

2. **The hold tube measurements are used to calculate the particle residence time based on the product flow. The inside diameter (ID) is entered to the nearest hundredth (i.e. 2.45”).**

3. **The hold tube length is entered to the nearest whole inch (i.e. 245”).**

Instructions for 2541c

Item 17 – Other Critical Factors



17. OTHER CRITICAL CONTROL FACTORS *(Check all that apply)*

- 61 ☐ Percent Solids
- 62 ☐ Ratio of Solids to Liquids
- 63 ☐ Syrup Strength
- 69 ☐ Method of Preparation
- 70 ☐ Formulation
- 71 ☐ Rehydration *(specify method in 22)*
- 72 ☐ Particulates *(specify maximum size in 22)*
- 73 ☐ Other *(specify in 22)*

1. Other critical factors are ones specified by the Process Authority as being necessary to ensure the appropriate scheduled process is delivered to the product.
2. All blocks which apply to the product must be checked and if applicable the appropriate value must be entered under Item 22.

Instructions for 2541c

Item 18 – Container Dimensions

	18. CONTAINER DIMENSIONS (Inches and Sixteenths)			19. SCHEDULED PROCESS					20. MAXIMUM FOOD FLOW RATE (gal / min)	21. THRUPUT (containers / minute)
No.	Diameter or Length	Height or Width	Height	Minimum Initial [4] Temp (°F)	Time (sec)	Temp (°F)	Least Sterilizing Value (°F) [5]	Flow Correction Factor		
1					.		.	.		
2					.		.	.		
3					.		.	.		
4					.		.	.		
5					.		.	.		
6					.		.	.		

1. The purpose of this section is to provide the container dimensions. They must be entered in English Units. A separate line must be used for each container size.

2. The container dimensions must be listed in inches and sixteenths of an inch using four (4) digits.

   Ex.: A container which has a dimension of 3 1/16” would be written as 0301.

Instructions for 2541c

Item 19 – Scheduled Process

	18. CONTAINER DIMENSIONS (Inches and Sixteenths)			19. SCHEDULED PROCESS					20. MAXIMUM FOOD FLOW RATE (gal / min)	21. THRUPUT (containers / minute)
No.	Diameter or Length	Height or Width	Height	Minimum Initial [4] Temp (°F)	Time (sec)	Temp (°F)	Least Sterilizing Value (°F) [5]	Flow Correction Factor		
1					.		.	.		
2					.		.	.		
3					.		.	.		
4					.		.	.		
5					.		.	.		
6					.		.	.		

1. The purpose of this section is to list critical factors necessary to achieve commercial sterility of the product. There are five critical factors listed: Minimum Initial Temperature, Time, Temperature, Least Sterilizing Value, and Flow Correction Factor.

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Item 19 – Scheduled Process continued

2. **Minimum Initial Temperature is the temperature of the product entering the processor. For normal fluid products this value is not applicable, enter N/A. If it is a product which is steam infused, steam injected or has particulates enter the coldest initial temperature which can be used for the process.**

3. **Process Time (sec) is the minimum time required to achieve the scheduled process and is determined by the process authority. Enter the minimum time in seconds to the nearest hundredth of a second (i.e. 27.00).**

4. **Process Temperature is the minimum processing temperature of the product at the exit of the hold tube. Enter this value in whole degrees (°F). NEVER ROUND UP, 275.9°F would be entered as 275°F.**

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Item 19 – Scheduled Process continued

5. **Least Sterilizing Value is the F_o of the process expressed to the nearest tenth of a minute (i.e. F_o = 8.4).**

   This uses the standard death rate Z value of 18°F and reference temperature (T_{ref}) of 250°F.

   If another F_o is used, the value for Z and T_{ref} Must be specified below the last value entered on the 2541c.

6. **Flow Correction is the value entered to correct for either laminar or turbulent flow of the fastest particle.**

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Item 20 – Maximum Food Flow Rate

	18. CONTAINER DIMENSIONS (Inches and Sixteenths)			19. SCHEDULED PROCESS					20. MAXIMUM FOOD FLOW RATE (gal / min)	21. THRUPUT (containers / minute)
No.	Diameter or Length	Height or Width	Height	Minimum Initial[4] Temp (°F)	Time (sec)	Temp (°F)	Least Sterilizing Value (°F)[5]	Flow Correction Factor		
1					.		.	.		
2					.		.	.		
3					.		.	.		
4					.		.	.		
5					.		.	.		
6					.		.	.		

1. This is the flow rate of the processing system measured as gallons per minute (gpm).
2. Enter the value to the nearest hundredth of a gallon.

Item 21 –Thruput

1. This is the thruput of containers for the packaging system.
2. Enter the value specified by the Process Authority in whole containers per minute.

Instructions for 2541c

Item 22 – Comments

1. The purpose of the comments section is to provide an area to enter specific information about a critical factor or an attachment.

2. Flow correction values, for steam infusion or steam injection systems which require flow correction when flow rate is measured prior to heating, should be entered here. Additionally, if the flow rate is measured after steam injection or infusion heating, this should be noted in the comment block.

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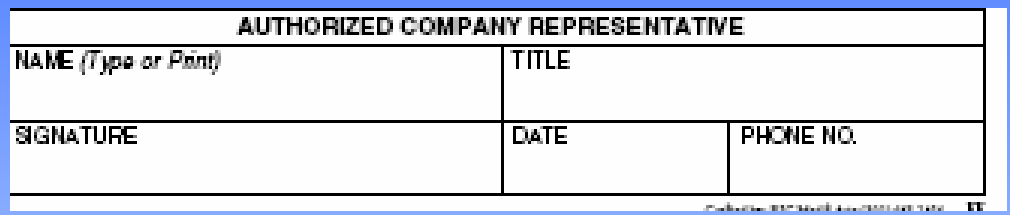
Authorized Company Representative



AUTHORIZED COMPANY REPRESENTATIVE		
NAME *(Type or Print)*	TITLE	
SIGNATURE	DATE	PHONE NO.

1. Enter the name, title, address, telephone number and signature of the authorized company representative who signs the form on behalf of the company.

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Standard vs. Electronic Filing

1. If this is a standard submission the original (white copy) is sent to: LACF Registration Coordinator (HFF-618)
2. The duplicate (pink copy) is kept on file at the plant location.
3. In an effort to reduce paper, plants are encouraged to use the electronic FDA Unified Registration and Listing System (FURLS).
4. Additional 2541c filing instructions are listed on the FDA CFSAN website:

www.cfsan.fda.gov/~comm/lacf-s6.html

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