# Instructions for Paper Submission of Form FDA 2541 (Food Canning Establishment Registration) for an Acidified/Low-Acid Food Canning Establishment

U.S. Department of Health and Human Services
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Center for Food Safety and Applied Nutrition
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### I. Introduction

This document is intended for:

- Commercial processors who manufacture, process, or pack acidified foods (AF) and/or thermally processed low-acid foods packaged in hermetically sealed containers (historically referred to as "low-acid canned foods" or "LACF")<sup>1</sup>; and
- Persons who are authorized to act on behalf of such commercial processors<sup>2</sup>.

Commercial processors who manufacture, process, or pack AF and/or LACF are subject to the registration requirements of 21 CFR 108.25(c)(1) (for AF) or 21 CFR 108.35(c)(1) (for LACF), as well as the process filing requirements of 21 CFR 108.25(c)(2) (for processors of AF) or 21 CFR 108.35(c)(2) (for processors of LACF). 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 2541e (Food Process Filing for Acidified 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:

 Register a new Food Canning Establishment (FCE) by paper submission using Form FDA 2541;

- Change registration information for the FCE;
- Change the list of products manufactured, processed or packed at the FCE; and
- Cancel registration for an FCE (e.g., if production ceases or there is a change in ownership).

<sup>1</sup> 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.

<sup>&</sup>lt;sup>2</sup> Individuals who act as authorized representatives may do so for more than one commercial processor. Reference 1 identifies the responsibilities of each type of authorized user.

This document does not provide instructions for submitting Form FDA 2541 in electronic format or for submitting process filing forms in either electronic or paper format. You can obtain information about submitting Form FDA 2541 in electronic format, and about submitting process filing forms in either electronic or paper format, from 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 to Reference 1).

# II. How to Submit Registration Form FDA 2541 by Paper

#### A. General Information

The paper Form FDA 2541 contains 5 sections (Sections 1 through 5).

• All fields marked with an asterisk in these instructions under section II.C, D, and F are mandatory and must be completed.

At the top right hand portion of the form is a box "For FDA Use Only" that identifies the "FCE number" and "Date Received by FDA." FDA will complete this section and send you a copy of the form with this information added.

To register with FDA, processors must complete FDA Form FDA 2541 for each processing establishment location and submit to the mailing address for FDA listed under Section IV of these instructions.

We recommend that the individual completing the form make and keep a copy of the registration form.

# B. Section 1: Type of Submission

There are three choices available under this section of the form: Initial Registration, Relocation, and Change of Registration Information. See the Appendix of this document for examples of a completed form for each of these choices.

#### **Initial Registration**

If the processing plant location has never been registered, select this choice and continue to Section 2.

### **Relocation (new registration required)**

If you have a previously registered FCE number and you are moving to a new location, select this choice, enter the current FCE number in the space provided, and continue to Section 2.

Relocating a facility will lead us to cancel the existing registration. You must therefore send us a separate Form FDA 2541 to register the new location. We will provide you with a new FCE number for the new location. We will work with you on a case-by-case basis to determine the impact of the relocation of the facility on the SIDs you previously filed.

### **Change Registration Information**

If you are submitting changes for a previously registered firm, select this choice, enter the current FCE number in the space provided, and continue to Section 3. Select "Change Registration Information" if one of the following types of scenarios apply:

- Change in firm name;
- Change in mailing address
- Change in ownership;<sup>3</sup>
- Change in postal address because of renaming of street, renumbering of building, etc. (no actual change in location);
- Cancellation of FCE

Specific instructions on how to change registration information are provided below, in Section III.A of these instructions. Specific instructions on how to cancel an FCE are also provided below, in Section III.B.

You must notify us not later than 90 days after ceasing or discontinuing the manufacture, processing, or packing of the foods in any establishment, except that you need not do so for temporary cessations due to the seasonal character of production or due to temporary conditions (e.g., labor disputes or fire) (21 CFR 108.25(c)(1) and 21 CFR 108.35(c)(1)). To notify us, you may either follow the instructions in Section III.B to cancel your registration using Form FDA 2541, or you may notify us using the contact information provided in Section IV.

You are not required to resubmit Form FDA 2541 to tell us about new products that you are going to begin manufacturing, processing, or packing at an establishment that you have already registered. The procedure you are required to follow for you to inform us about such new products is to submit process filing forms (see Section I of this document and Reference 1 for more information about process filing). You are also not required to resubmit Form FDA 2541 to tell us when you no longer manufacture, process, or pack products you previously listed on the form. You may, however, voluntarily choose to use

<sup>&</sup>lt;sup>3</sup> A change in ownership will lead us to cancel the existing registration and all process filing forms submitted under the applicable FCE number. The new owner must submit a new Form FDA 2541 (Food Canning Establishment Registration), in response to which we will send the new owner a new FCE number. At that point the new owner must submit new process filing forms for all LACF and AF products that will be manufactured, processed, or packed under the new ownership. The new process filing forms will need to include the new FCE number we will assign in response to the new owner's registration. If the new owner has any questions about the process for submitting new process filing forms, the new owner may contact FDA using the contact information provided in Section IV of these instructions.

Form FDA 2541 to tell us when you no longer manufacture, process, or pack such products.

Do not use Form FDA 2541 to provide us with updated information about your Establishment Contact Person (ECP). If you wish to designate a new ECP and/or provide us with updated contact information for your ECP, you may do so by contacting us using the contact information provided in Section IV of these instructions.

### C. Section 2: Food Processing Plant Location

Section 2 of the form has data entry fields for the location of the food processing plant. See a list of required and optional fields immediately below. Fields marked with an asterisk (\*) below under this section of the instructions are required.

\*Establishment Name - The name of the food processing plant at the location being registered.

\*Number and Street - The physical address of the food processing plant at the location being registered. This is normally a street address, but may be some other physical/geographical designation used in rural locations.

\*City and State or Province (or other Subdivision) - The city and State or Province where the food processing plant is located.

\*Zip (or other Postal Code) - The Zip Code (domestic) or Postal Code (foreign) corresponding to the food processing plant at the location being registered.

\*Country (if other than U.S.) – The country name of the establishment where the food processing plant is located.

\*Telephone No. - The telephone number where the food processing plant is located as reported on the FFR registration.

TeleFax No. - The fax number, if applicable.

### D. Section 3: Preferred Mailing Address

Section 3 of the registration form has data entry fields for the preferred mailing address, which may be different from the physical location of the establishment. This preferred mailing address will be used for all FDA correspondence regarding registration and process filing. There are two scenarios with respect to the preferred mailing address:

- Scenario 1: If the preferred mailing address is the same as the food processing plant location identified in Section 2, check the "Same as Plant Location" box.
- Scenario 2: If the preferred mailing address is different from the food processing plant location identified in Section 2, do not check the "Same as Plant Location" box. Instead, enter the applicable information in the required and optional fields. You may enter a Post Office (P.O.) box number instead of street address and number, if applicable.

See a list of required and optional fields immediately below. Fields marked with an asterisk (\*) below under this section of the instructions are required.

\*Establishment Name - The name of the company as you wish it to appear on any mailing information. \*Number and Street - The address for all mail correspondence.

\*City and State or Province (or other Subdivision) - The city and State or Province for all mail correspondence.

\*Zip (or other Postal Code) - The Zip Code (domestic) or Postal Code (foreign) for all mail correspondence.

\*Country (if other than U.S.) – The country name of the establishment for the preferred mailing address information for correspondence.

\*Telephone Number - The applicable telephone number.

TeleFax Number - Any applicable fax number.

# E. Section 4: Low Acid and/or Acidified Foods Processed at this Location

Section 4 of the registration form has data entry fields to create a list of all the AF and/or LACF products that are manufactured, processed, or packed at the FCE location. Products processed under the continuous inspection of the meat and poultry inspection program of the Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture under the Federal Meat Inspection Act or the Poultry Products Inspection Act are not covered by 21 CFR 108.25 or 108.35. Therefore, do not list meat and poultry foods under the jurisdiction of the FSIS. Describe the actual food commodity or formulated food in the container (e.g., beans, green; mushrooms (button); tuna (light); sardines (sild)).

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., green kidney beans (flageolets) in brine).

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., mushrooms (Agaricus bisporus) pieces and stems, in brine; Beans (Phaseolus vulgaris) in brine).

Select either Low Acid or Acidified, depending on whether the product is a low-acid food or an acidified food.

### F. Section 5: Establishment Contact Person

Section 5 of the registration form has data entry fields for contact information for the Establishment Contact Person (ECP). An ECP should be an authorized, responsible official with the processing plant or with the facility's corporate office, or an individual authorized by the facility to act on behalf of the facility. Check the appropriate box for "Position" of the ECP. See a list of required and optional fields immediately below. Fields marked with an asterisk (\*) below under this section of the instructions are required.

\*Name of Contact and Business Address - The first and last name of the person who is authorized to represent the facility as the ECP, as well as the ECP's business address. If the ECP's business address is not the same as the processing plant location, include the applicable business address.

\*Position - The position of the ECP as described below:

- Owner Owner of the processing plant or the corporate office.
- Technologist Technologist employed at the processing plant or the corporate office.
- Manager Manager employed at the processing plant or the corporate office.
- Director Director employed at the processing plant or the corporate office.
- President/Vice President President/Vice President of the processing plant or the corporate office.
- Other Employee An employee of the processing plant or corporate office who is NOT the Owner, Technologist, Manager, Director, or President/Vice President.
- Authorized Third Party A person other than an Owner, Technologist, Manager, Director, President/Vice President, or Other Employee who has been authorized by the commercial processor to submit the form on behalf of the commercial processor.

\*Phone Number – The phone number of the ECP.

FAX Number – The FAX number of the ECP.

Email Address - The email address of the ECP.

\*Signature - The signature of the ECP.

\*Date- The date of the signature of the ECP

### G. Notes

The right hand section of the form entitled "Please Note the Following" advises you that:

The requester hereby presents and acknowledges that the company is aware that in making this request the company is subject to the terms and provisions of Title 18, Section 1001, United States Code which makes it a criminal offense to falsify, conceal, or cover up a material fact; make any false, fictitious, or fraudulent statement or representation; or make or use any false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry.

Subject to the terms of 21 CFR 108.25 (c)(1) and (2) and 108.35 (c)(1) and (2), no commercial processor shall engage in the processing of low-acid or acidified foods until the completed Forms FDA 2541 and 2541d, 2541e, 2541f, and/or 2541g have been filed with the FDA within the applicable time frames specified in these regulations.

# **III.** How to Change or Cancel Registration Information

The ECP, or a user authorized to act on behalf of the ECP, may change registration information or cancel a registration after the registration has been submitted to FDA.

# A. Change Registration Information

To change registration information, do the following:

- Select Change Registration in the space provided. Enter the FCE number.
- Enter the reason for the change next to "Specify Type of Change" as discussed in Section I.
- Complete the information under the applicable section(s). You may skip the sections of Form FDA 2541 that are not applicable to the change in registration information.

• Return the completed signed and dated form to FDA using the contact information provided in Section IV of these instructions.

### **B.** Cancel Registration

You must notify us not later than 90 days after you cease or discontinue the manufacture, processing, or packing of the foods in any establishment, except that you need not do so for temporary cessations due to the seasonal character of your production or due to temporary conditions (e.g., labor disputes or fire) (21 CFR 108.25(c)(1) and 21 CFR 108.35(c)(1)).

There are two ways to cancel a registration using Form FDA 2541:

Make a copy of the original Form FDA 2541 that FDA provided to you that
included the FCE number, select the checkbox next to "Change Registration
Information," enter "Cancelation" in the space provided next to "Specify Type of
Change," and return the form to FDA using the contact information provided in
Section IV of these instructions;

Or;

- Using a blank Form FDA 2541, select the checkbox "Change Registration Information," and in the space provided enter the FCE number to be canceled.
- Enter "Cancelation" in the space provided next to "Specify Type of Change."
- Complete Section 5 and return the form to FDA using the information provided in Section IV of these instructions.

Alternatively, you may cancel a registration by contacting us using the contact information provided in section IV of these instructions.

# IV. 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

# V. References

1. <u>Guidance for Industry: Submitting For 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</u>

# VI. Appendix

## A. Examples of Completed FDA 2541 Registration Form

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1. TYPE OF SUBMISSION	MENT OF HEALTH AND Food and Drug Admini		RVICES		FOR F	DA USE ONLY				
	NING ESTABLISHME	STABLISHMENT REGISTRATION				Date Received	by FDA			
Relocation (new registration required) Enter Current FCE: (if applicable)										
Change Registration Information Enter Current FCE: (If applicable)										
Specify Type of Change:										
2. FOOD PROCESSING PLANT LOCATION	3. PR	EFERRE	D MAILING AD	DRESS 🖂	Same as Plant	Location				
Establishment Name ABC Co.	Establis Name	Establishment								
Number and Street 123 Main St	Numbe Street	r and								
City and State	City an									
or Province (or other Subdivision) Columbia, SC		or Province (or other Subdivision)								
Zip (or other Postal Code) 12345 Country (if other than U.S.)		Zip (or other   Country (if other   Postal Code)   than U.S.)								
Telephone No. (410) 333-1234 Telefax No. (410) 444-1212	Telepho	one No.			Telefax No.					
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Figure 1 – Example of FDA 2541 for a New Registration

		FORM APP	ROVED: O	MB No. 0910-0037;	EXPIRATION DAT	E: 02-28-2015	o. (See PKA statement on page 2.)	
1. TYPE OF SUBMISSION	LTH AND		SERVICES	FOR FDA USE ONLY				
Initial Registration	FOOD CANNING ESTA	BLISHME	ENT REC	SISTRATION	FCE No.		Date Received by FDA	
Relocation (new registration required) Enter Curre	ent FCE: (If applicable) 00000							
Change Registration Information Enter Current	FCE: (If applicable)							
Specify Type of Change:								
2. FOOD PROCESSING PLANT LOCATION Establishment Name  ABC Co.			REFERRI shment	ED MAILING A	DDRESS 🖂	Same as Plan	nt Location	
Number and Street 123 Main St		Numbe	er and					
Street 125 Main St City and State or Province (or other Subdivision) Columbia, SC		Street City and State or Province (or other Subdivision)						
Zip (or other Postal Code) 12345 Country (if other than U.S.)		Zip (or Postal			try (if other U.S.)			
Telephone No. (410) 333-1234 Tel	efax No. (410) 444-1212	Teleph	one No.			Telefax No.		
(Do not list meat and poutry foods under the jurisdiction of the Department of Agriculture.)	Food Safety and Inspection Service of the U.S.	Low-Acid	Acidified	statement or re	presentation; or	make or use a	y false, fictitious, or fraudulent any false writing or document knowin ious, or fraudulent statement or entry	
	his location is not a process filling.	(Chec	k One)	Section 1001, I	United States Co	de which mak	the terms and provisions of Title 18 tes it a criminal offense to faisify,	
Tuna in water		X		the same to co	ntain any materia	ally false, fictiti	ious, or fraudulent statement or entry	
Artichokes (whole) in brine				commercial pro	cessor shall eng	age in the pro	and (2) and 108.35 (c)(1) and (2), no occessing of low-acid or acidified food	
The state of the s		H					1d, 2541e, 2541f or 2541g have bee rames specified in these regulations.	
				<ul> <li>Forms, Instruct www.fda.gov/F</li> </ul>	tion can be secured online at http://			
				GuidanceDocu				
				<ul> <li>For more information in the second in the sec</li></ul>		e LACF Regis	gistration Coordinator by e-mail at	
				Food and	Drug Admin	istration		
				LACF Reg	gistration Co	ation Coordinator (HFS-303)		
			Center for Food Safety & Applied Nutrition 5100 Paint Branch Parkway					
					ark, Marylan		835	
John Smith, ABC Co	5. ESTABLISHMENT ., 444 River St., Columbia, SC 33333	CONTA	CT PER	SON				
e of Contact and Business Address:	□ Director □ PresidentVice Presid	dent 🔲 d	Other Emplo	eyee Authorize	ed Third Party P	hone Number:	410-555-1212	
	Address: john_smith@abcco.com		ignature:		,		h Date: 06/09/2014	
FORM FDA 2541 (1/13) PREVIOUS EDITION	n	e 1 of 2					PSC Publishing Staveces (301) 443-6740 E	

Figure 2 - Example of FDA 2541 Relocation of Establishment

	DEPARTMENT OF HEAL	TH AND HUMAN S		EXPIRATION DATE: 0	FOR FDA USE ONLY	rvi statement on page 2			
TYPE OF SUBMISSION     Initial Registration	Food and Dr FOOD CANNING ESTAB	ug Administration BLISHMENT REG	SISTRATION	FCE No.	5 - 5 - 5 - 5 - 5 - 5 - 5 - 5 - 5 - 5 -	eived by FDA			
Relocation (new registration required) Enter Currer	nt FCE: (If applicable)								
Change Registration Information	FCE: (If applicable) 11111	-							
Specify Type of Change: cancelation									
2. FOOD PROCESSING PLANT LOCATION Establishment Name ABC Co.		3. PREFERRI Establishment Name	ED MAILING A	DDRESS Same	e as Plant Location				
Number and		Number and							
Street 123 Main St City and State or Province (or other Subdivision) Columbia, SC		Street City and State or Province (or other Subdivision)							
Zip (or other Postal Code) 12345 Country (if other than U.S.)		Zip (or other Postal Code)		try (if other U.S.)					
Telephone No. (410) 333-1234 Tele	fax No. (410) 444-1212	Telephone No.		Tele	efax No.				
Vegetable Soup			the same to contain any materially false, ficitious, or fraudulent statems  Subject to the terms of 21 CFR 108.25 (c)(1) and (2) and 108.35 (c)(1)  commercial processor shall engage in the processing of low-acid or act until the completed forms FDA 2541 and 2541d, 2541e. 2541f or 2541g  filled with the FDA within the applicable time frames specified in these re						
			cured online at http://						
			Food and						
		linator (HFS-303) Applied Nutrition ay 0740-3835	ı						
	5. ESTABLISHMENT	CONTACT PER	SON	•					
of Contact and Business Address: John Smith, ABC Co.	444 River St., Columbia, SC 33333	ent Other Emplo	- La succio	nd Third Party Phone	Number: 410-555-1	1212			
C manager	ddress: john_smith@abcco.com	Signature:	yee i Authorize	id Illiid Party	h	te: 06/09/2014			
COPM EDA 2541 (1/12) BREVIOUS EDITION	n	1 of 2				WAS obtained State (1901) 443-4740			

Figure 3 –Example of FDA 2541 Cancellation of Establishment