Contains Nonbinding Recommendations

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:

Guidance for Industry

Additional copies are available from:
Office of Food Safety
Food Processing Evaluation Team, HFS-302
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5001 Campus Drive
College Park, MD 20740
(Tel) 240-402-2411
http://www.fda.gov/FoodGuidances

You may submit electronic or written comments on this guidance at any time. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the Docket No. FDA–2013–D–1622.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition

November 2016

Table of Contents

Submitting Form FDA 2541 (Food Canning Establishment Registration) and FDA Forms 2541d, 2541e, 2541f, and 2541g (Food Process Filing Forms) to FDA in Electronic or Paper Format: Guidance for Industry[1]

I. Introduction

This guidance 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")[2]; and

- Persons who are authorized to act on behalf of such commercial processors[3].

[1] This guidance has been prepared by the Food Processing Evaluation Team in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

[2] 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.

[3] Individuals who act as authorized representatives may do so for more than one commercial processor. Table 1 identifies the responsibilities of each type of authorized user.

Commercial processors who manufacture, process, or pack AF and LACF are subject to the registration requirements of 21 CFR 108.25(c)(1) (for AF) and 21 CFR 108.35(c)(1) (for LACF), as well as the process filing requirements of 21 CFR 108.25(c)(2) (for AF) and 21 CFR 108.35(c)(2) (for LACF). These provisions require two basic types of submissions:

- Food Canning Establishment Registration using Form FDA 2541; and
- Process filings using the following forms, as applicable:
  - 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 guidance describes:

- Administrative procedures relating to the registration and process filing requirements of 21 CFR 108.25(c) (for AF) and 21 CFR 108.35(c) (for LACF);
- Administrative procedures for voluntary registration and voluntary submissions for certain products manufactured, processed, or packed by a commercial processor who has determined that the products are not subject to the registration and process filing requirements of 21 CFR 108.25(c) (for AF) or 21 CFR 108.35(c) (for LACF); and
- A voluntary process whereby, upon request, we review data and other information that relate to a new processing method or new equipment.

This guidance addresses two basic types of submissions, described above, that are required for AF and LACF:

- Food Canning Establishment Registration using Form FDA 2541 (see Appendix 10); and
- Process filings using Forms FDA 2541d, FDA 2541e, FDA 2541f, or FDA 2541g (see Appendices 1 through 4, respectively).

This guidance also provides general information about how to use FDA's systems for electronic submission of these forms. We recommend that you submit these forms electronically and are issuing this guidance as a general aid to enable you to do so.

This guidance does not provide detailed instructions on how to complete electronic or paper submissions of Forms FDA 2541, 2541d, 2541e, 2541f, and 2541g. Such instructions are available elsewhere. (See Appendix 11 for instructions for electronic submission of Form FDA 2541, Appendix 12 for instructions for paper submission of Form FDA 2541, and Appendices 5 through 8 for instructions for paper submission of Forms FDA 2541d, 2541e, 2541f, and 2541g).

In the remainder of this guidance, "you" refers to:

- Commercial processors who manufacture, process, or pack AF or LACF;
- Commercial processors who manufacture, process, or pack products that they have determined are not AF or LACF, but who wish to voluntarily submit information about such products to FDA; and
- Persons who are authorized to act on behalf of such commercial processors.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe our current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in our guidances means that something is suggested or recommended, but not required.

II. Background

A. Requirement for Registration

A commercial processor, when first engaging in the manufacture, processing, or packing of AF or LACF, shall, not later than 10 days after first so engaging, register and file with FDA information including the name of the establishment, principal place of business, the location of each establishment in which that processing is carried on, the processing method, and a list of foods so processed in each establishment (21 CFR 108.25(c)(1) and 21 CFR 108.35(c)(1)). You do so by submitting a separate Form FDA 2541 for each physical processing plant. You may register electronically (using the instructions in Appendix 11) or on paper (using the instructions in Appendix 12). After you register an establishment, we assign a Food Canning Establishment (FCE) number identifying the physical processing plant located at the address identified on Form FDA 2541.

For example, to register one processing plant located at 123 Main Street, Camden, New Jersey and another processing plant located at 123 Oxford Road, Alexandria, Virginia, you would file two separate FDA Forms 2541 - one for the processing plant located in New Jersey and another for the processing plant located in Virginia. We would assign a unique FCE number to each processing plant.

Form FDA 2541 includes information identifying an "Establishment Contact Person" (ECP) for the establishment being registered. 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. When a commercial processor has more than one establishment at distinct physical locations (e.g., in New Jersey and Virginia), a single individual may serve as ECP for more than one establishment.

Importantly, if you use our electronic system for submitting your process filings, the ECP will have authority to grant additional individuals access to your electronic FCE information, and those individuals will be able to see any trade secret information or other confidential information that you include in your process filing submissions. For this reason, we recommend that you take care in determining who will serve as your ECP. For more information on how the ECP grants access to individuals to your electronic account, including access to any trade secret information or other confidential information that you include in your process filing submissions, see section IV.D of this guidance.

B. Requirement for Process Filing

A commercial processor engaged in the processing of AF shall, not later than 60 days after registration, and before packing any new product, provide FDA with information (using Form FDA 2541e) on the scheduled processes for each acidified food in each container size (21 CFR 108.25(c)(2))[4]. An analogous requirement for process filing, using either Form FDA 2541d, Form FDA 2541f, or Form FDA 2541g, applies to a commercial processor of LACF (21 CFR 108.35(c)(2)).[5]

When you submit a process filing form, you include the FCE number for the location of the processing plant where the product will be manufactured, processed, or packed (Appendices 1 through 4). Including the FCE number on the process filing form links your process filing to your establishment. You may submit process filing forms either electronically or on paper.

We will consider you to have complied with 21 CFR 108.25(c)(2) or 108.35(c)(2) as of the date on which we receive your completed process filing (Form FDA 2541d, FDA 2541e, FDA 2541f or FDA 2541g), whether electronically or on paper. If your form is incomplete—for example, because you have left some sections blank, or because you have filled in some sections in a way that is non-responsive—we will inform you in one of two ways. For paper submissions, we will contact you using your preferred mailing address, as identified on Form FDA 2541. We will treat the product identified on the form as not having complied with 21 CFR 108.25(c)(2) or 108.35(c)(2) until we receive a completed process filing. For electronic submissions, you will receive immediate feedback during the submission process to prevent blank or non-responsive sections on the forms.

We review the submitted information about the scheduled processes for your products. Under 21 CFR 108.25(c)(3)(ii) and 108.35(c)(3)(ii), we may request that you provide us with any process and procedure information that we deem necessary to determine the adequacy of the process.

A "Submission Identifier" (SID) identifies each process filing (Appendices 5 through 8). The SID consists of (1) the year, month, and day of the month that a process filing form is created, and (2) a unique sequence number to identify each form when multiple forms are created on the same date. The SID enables both you and FDA to quickly and accurately identify a specific process filing. Because all filed process filings have a SID, it is common practice to refer to a filed process filing as a SID and to refer to a FCE's collection of process filings as its SIDs. When you use the electronic AF/LACF system to create a process filing, the system automatically generates a SID. When you create a process filing using a paper form, you generate the SID yourself and include it on the paper form.

C. Voluntary Registration and Voluntary Submissions

[4] The regulation currently specifies Form FDA 2541a. We intend to update the regulation to specify the new form.
[5] The regulation currently specifies Form FDA 2541a (food canning establishment process filing for all methods except aseptic) or Form FDA 2541c (food canning establishment process filing for aseptic systems). We intend to update the regulation to specify the new forms.

Processors who have determined that their specific food products are not acidified foods (or low-acid canned foods) sometimes provide us with information about these products by registering using Form FDA 2541 and then voluntarily submitting Form FDA 2541e as a voluntary submission for these products. If you conclude that a specific food product does not meet the definition of an acidified food at 21 CFR 114.3(b) and you choose to voluntarily submit process information about that product using Form FDA 2541e, we will evaluate that information to determine whether it is consistent with your conclusion.

- If the conclusions of our evaluation are not consistent with yours, we may request additional information to help us evaluate your product or advise you that your product appears to be an acidified food subject to 21 CFR Part 114 and 21 CFR Part 108.
- If the conclusions of our evaluation are consistent with yours, we will list your product in our paper and electronic files as a voluntary submission that is not subject to either 21 CFR Part 113 or 21 CFR Part 114.
    - If you have an online AF/LACF account to submit and view process filings electronically, you can see this status for your product when you access your online account.
    - If you submitted your voluntary submission using a paper form, and do not have an online AF/LACF account, we will respond to you using the same method by which you submitted your request (i.e., either written or email) if you specifically ask us to do so.

We will make available to our investigators the results of our evaluation for use during inspection of your facility, or when food is offered for import, to facilitate their determinations regarding the regulatory status of your products.

If you choose to submit to FDA process information regarding a food that you conclude is not an acidified food, we recommend that you:

- Register your facility using Form FDA 2541(Appendix 10) if you have not done so previously (e.g., because you do not also process any acidified foods or low-acid foods). Doing so will enable you to complete the process filing form (Form FDA 2541e), which requests the Food Canning Establishment (FCE) number we assign to your facility when you register using Form FDA 2541; and
- Follow the instructions for submitting Form 2541e for acidified foods (Appendix 6). These instructions indicate the portions of Form 2541e that are to be filled out by voluntary filers.

D. Voluntary Process for FDA Evaluation of New Processing Methods or New Equipment

If you choose to do so, you may submit data and other information that relate to a new processing method or new equipment. If you do so, we will review that data and other information as a courtesy in advance of a process filing. If we have questions about the new processing method or new equipment, we will discuss them with you. If we have no such questions, we will send you a letter (a "No Questions Letter") to that effect.

Importantly, a No Questions Letter from us neither constitutes our approval of the method or system nor substitutes for a process filing required under 21 CFR 108.25(c)(2) or 21 CFR 108.35(c)(2).

III. Portals for Electronic Submissions

A. FDA's Industry Systems (FIS)

An electronic portal called "FDA Industry Systems" (FIS) provides general entry to a series of specific systems for electronic submissions to FDA. To use the electronic FIS portal, follow the instructions in Appendix 13 to obtain an FDA Account ID and password.

B. FDA's Unified Registration Listing Systems (FURLS)

FDA's Unified Registration Listing System (FURLS) is a specific component of the general FIS electronic portal. Systems within the FURLS component enable persons with an FDA Account ID and password for the FIS electronic portal to register a facility electronically. The two FURLS systems that are relevant to this document are:

- Food Facility Registration (FFR); and
- Acidified/Low-Acid Canned Foods.

C. Relationship Between the Electronic Acidified Food/Low-Acid Canned Food Registration System and Food Facility Registration (FFR)

The registration requirement in 21 CFR Part 108 for FCEs that manufacture, process, or pack AF or LACF product is not the same as the FFR system. The FFR system stems from the requirement in section 415 of the Federal Food, Drug, and Cosmetic Act ("FD&C Act") that domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States must register with FDA.[6] The registration requirement in section 415 of the FD&C Act was created by the Public Health Security and Bioterrorism Preparedness Act of 2002 (the "BT Act") and amended by the FDA Food Safety Modernization Act (FSMA) (Pub. L. 111-353). AF and LACF commercial processors must register with FDA as required in 21 CFR Part 108 using FDA Form 2541, and must also register with FDA under the FFR system using FDA Form 3537 as required by section 415 of the FD&C Act. We use the term "FFR" interchangeably with the term "BT Act registration."

The design of the electronic AF/LACF registration system links it to the FFR system. Specifically, the electronic system for submission of Form FDA 2541 is limited to facilities that are registered as food facilities pursuant to section 415 of the FD&C Act. Facilities that register

[6] See the requirements in 21 CFR Part 1, subpart H (FDA's food facility registration regulations) and FDA's guidance entitled "What You Need to Know About Registration of Food Facilities" (Ref. 1) to determine whether you are subject to the requirement to register as a food facility pursuant to section 415 of the FD&C Act.

in the FFR system receive a facility registration number and PIN. During the FFR process, or during an update to a facility's FFR submission, you can identify your facility as an Acidified/Low-Acid Food Processor.

The electronic AF/LACF registration system in FURLS becomes available to you if your registration in the FFR system identifies your facility as an Acidified/Low-Acid Food Processor. If your facility is registered in the FFR system, but you have not yet identified yourself as an Acidified/Low-Acid Food Processor, you can update your FFR information to add this information.

If you are not required to register as a food facility under FDA's food facility registration regulations, and you want to access the electronic AF/LACF system, see section IV.A of this guidance for information about two methods for doing so.

IV. Overview of Processes for Submission of Registration and Process Filing Forms

A. Create an FDA Account, Register as a Food Facility, and Identify Your Facility as an Acidified/Low-Acid Food Processor

If you want to make all submissions using paper forms, skip this step and go to section IV.B of this guidance.

If you want to use the electronic AF/LACF system:

- If you have not already done so, create an FDA Account for the electronic FIS portal by following the instructions in Appendix 13 to obtain your FDA Account ID and password.
- If you have not already registered the establishment as a food facility in accordance with 21 CFR Part 1 Subpart H (i.e., BT Act Registration), do so by following the instructions in Appendix 14 to obtain an FFR number and PIN. During the registration process, identify the food facility as an Acidified Food Processor and/or Low-Acid Food Processor under Section 9a "General Product Categories – Food for Human Consumption; and Type of Activity Conducted at the Facility" and/or 9b "General Product Categories – Food for Animal Consumption; and Type of Activity Conducted at the Facility" (see Appendix 14). It is not necessary for the person who submits the food facility registration in the FFR system to be the same person as the Establishment Contact Person (ECP) for the AF/LACF system. For example, Mr. Smith can submit the food facility registration in the FFR system and Mr. Jones can be the ECP in the AF/LACF system. However, Mr. Smith and Mr. Jones will each need an individual FDA Account and password for the FIS portal. Refer to section II.A for the definition of an ECP.

- If the establishment is not required to register as a food facility under FDA's food facility registration regulations(21 CFR Part 1 Subpart H)(i.e., BT Act Registration) , you may either:

- Follow the Instructions in Appendix 14 to register the establishment voluntarily and obtain an FFR number and PIN so that you can submit Form FDA 2541 electronically; or

- Follow the Instructions in Appendix 12 to submit Form FDA 2541 using a paper form; tell us that you want to access the electronic AF/LACF system when you send us your paper registration form, and provide us with your FDA Account ID for the FIS electronic portal.

- If you already registered the establishment as a food facility and have an FFR number and PIN, but you have not yet identified the food facility as an Acidified Food Processor and/or Low-Acid Food Processor, you must update the FFR registration information (21 CFR 1.234). Under Section 9a "General Product Categories – Food for Human Consumption; and Type of Activity Conducted at the Facility" and/or 9b "General Product Categories – Food for Animal Consumption; and Type of Activity Conducted at the Facility", check the appropriate activity type(s) as Acidified Food Processor and/or Low Acid Food (see Appendix 14).

- After identifying the registered food facility as an Acidified Food Processor and/or Low-Acid Food Processor, log out of your FDA account and then log back in. After you log back in, the system will provide you with access to the electronic Acidified /Low Acid Canned Food system.

B. Register as a Food Canning Establishment by Submitting Form FDA 2541

We recommend that you register an establishment electronically. To do so, follow the instructions in Appendix 11 to register the establishment by electronic submission of Form FDA 2541.

If you prefer to register the establishment by paper submission of Form FDA 2541, follow the instructions in Appendix 12 to do so.

C. FDA Receives Form FDA 2541

If you use the electronic AF/LACF system to register an establishment, the electronic registration system will automatically assign an FCE number, display a message informing you of the assigned FCE Number, and send an email including a copy of the submitted Form FDA 2541 to the Establishment Contact Person (ECP). If we have questions concerning your submitted registration information, we may contact the ECP using contact information included with the registration.

If you register an establishment using a paper form, we will assign an FCE number and provide it to the Preferred Mailing Address identified on Form FDA 2541.

If you register an establishment using a paper form and also ask us to provide access to the electronic AF/LACF system, the ECP will need to provide FDA with the ECP's FIS Account ID. We will then link the electronic AF/LACF system to the ECP's FDA Account ID (see the discussion of the FIS portal in section III). After we do so, the electronic AF/LACF system will become available to the ECP when the ECP next logs into the ECP's FDA Account. We will inform the ECP when the electronic AF/LACF system is ready for use.

D. Establishment Contact Person Authorizes Individuals to Access the Electronic Acidified Food/Low-Acid Canned Food System for the Food Canning Establishment

As discussed in section II.A of this guidance, we recommend that a commercial processor select its ECP with care, as the ECP will have authority to grant additional individuals access to the establishment's process filing information, including trade secret information and confidential data. 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.

The ECP may authorize one or more individuals to access the electronic AF/LACF system for a specific FCE and perform designated functions related to process filing. Doing so is not necessary and is at the discretion of the ECP. Such individuals may be your employees or authorized third parties.[7] We recommend that the ECP grant access only to individuals the ECP trusts with the establishment's process filing information, including trade secret information and confidential data. The ECP can use the electronic AF/LACF system to authorize individuals to perform functions related to process filing. However, at this time only the ECP and the Super Authorized Representative (Super AR, described below) are authorized to perform functions related to registration.

The ECP authorizes an individual to access the electronic AF/LACF system for a particular FCE by assigning a role to the individual as Super AR, an Authorized Representative (AR), or a Read Only Access Representative (ROAR). A particular FCE can only have a single ECP but may have more than one Super AR, AR and/or ROAR. The assigned role determines the functions the individual can perform electronically and when contacting FDA on behalf of the ECP. Table 1 shows the authorized functions that can be performed by the ECP, Super AR, AR, and ROAR.

Table 1. **Authorized Functions Associated with Assigned Roles**

Authorized Functions	Establishment Contact Person (ECP)	Super Authorized Representative (Super AR)	Authorized Representative (AR)	Read-Only Authorized Representative (ROAR)

[7] Individuals who act as authorized third party representatives may do so for more than one commercial processor.

Authorized Functions	Establishment Contact Person (ECP)	Super Authorized Representative (Super AR)	Authorized Representative (AR)	Read-Only Authorized Representative (ROAR)
Submit initial FCE Registration Form 2541	Yes	No	No	No
Access the FCE's electronic AF/LACF Online Account	Yes	Yes	Yes	Yes
Assign roles	Yes	No	No	No
Assign AR to process filing	Yes	No	No	No
Update FCE registration information	Yes*	Yes*	No	No
Discuss FCE registration information with FDA	Yes	Yes	No	No
Submit process filings	Yes	Yes	Yes	No
Discuss process filings with FDA	Yes	Yes	Yes	No
Search, print, and view process filing in the FCE's electronic AF/LACF Online Account	Yes	Yes	Yes	Yes
Provide additional information to FDA (e.g., upon request) by mail, E-mail, or fax	Yes	Yes	Yes	No

*At this time, the system only allows the ECP to update registration information electronically. A Super AR who needs to discuss and/or update the registration information electronically needs to contact FDA using the contact information provided in section VI of this guidance.

E. Submit Process Filing Forms

As described above, process filing forms can be submitted by the ECP, Super AR, or AR. We recommend that you submit your process filing forms electronically. However, you can also submit your process filing forms on paper.

V. Changes to AF/LACF Registration Information

A. Changing the Establishment Contact Person

To change the ECP, contact us using the contact information provided in section VI of this guidance.

B. Changing the Mailing Address for the Food Canning Establishment

To change the mailing address for the FCE, follow the instructions in Appendix 11 to do so electronically or in Appendix 12 to do so by paper submission of Form FDA 2541.

C. Changing the Telephone Number and Email Address for the Establishment Contact Person, and Changing the Establishment Contact Person

To change the telephone number or email address for the ECP electronically, or to designate a new ECP, you may contact FDA using the contact information provided in Section VI of these instructions.

D. Adding or Deleting Product Information

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 to inform us about such new products is to submit process filing forms. 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 Form FDA 2541 to tell us when you no longer manufacture, process, or pack such products. If you voluntarily choose to do so, follow the instructions in Appendix 12 to do so electronically or in Appendix 11 to do so by paper submission of Form FDA 2541.

E. Cancelling Registration

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, follow the instructions in Appendix 11 to cancel the registration by electronic submission, or follow the instructions in Appendix 12 to cancel the registration by paper submission. Alternatively, you may contact us using the contact information provided in section VI of this guidance.

In the case of a change in the ownership of the establishment to another person, you should submit a Form FDA 2541, following the instructions in Appendix 11 for electronic submissions or Appendix 12 for paper submission. 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 assign 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. 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 VI of this guidance.

F. Relocating Commercial Processing Operations

If commercial processing operations are relocated (i.e., the manufacture, processing, and packing of foods in one establishment ceases or is discontinued and some or all of those operations are relocated to a new establishment), you must submit a Form FDA 2541, following the instructions in Appendix 11 for electronic submissions or Appendix 12 for paper submission, and your existing registration will be canceled. If you notify us using the paper version of Form FDA 2541, we will cancel the existing registration. If you notify us using the electronic version of Form FDA 2541, the electronic system will allow you to cancel the registration yourself. You also must register the new establishment (see 21 CFR 108.25(c)(1) and 21 CFR 108.35(c)(1)). Follow the instructions in Appendix 11 to register the new establishment by electronic submission of Form FDA 2541 or follow the instructions in Appendix 12 to register the new establishment by paper submission of Form FDA 2541. 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.

G. Change in Street Information via Postal Service or Local Government

If the postal service or local government makes a change to the address where an existing establishment resides and there is no physical relocation, you may follow the instructions in Appendix 11 to notify us by electronic submission of Form FDA 2541, or follow the instructions in Appendix 12 to notify us by paper submission of Form FDA 2541. Alternatively, you may notify us using the contact information provided in section VI. FDA may ask questions intended to assure the agency that the establishment has not physically relocated. If you also need to change the FFR information, contact the FDA Industry Systems (FIS) help desk for further assistance (see Appendix 14.)

VI. 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
5001 Campus Drive
College Park, Maryland 20740-3835

Additional information about submitting registration and process filing forms for AF and LACF is available in the Appendices identified in section VIII of this guidance.

VII. References

1. FDA. 2012. What You Need to Know About Registration of Food Facilities. Accessible at http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm331957.htm

VIII. Appendices

1. FDA 2014: Form FDA 2541d. Food Process Filing for Low-Acid Retorted Method. Accessible at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM465591.pdf
2. FDA 2014: Form FDA 2541e. Food Process Filing for Acidified Method. Accessible at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM465593.pdf
3. FDA 2014: Form FDA 2541f. Food Process Filing for Water Activity/Formulation Control Method. Accessible at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM465595.pdf
4. FDA 2014: Form FDA 2541g. Food Process Filing for Low-Acid Aseptic Systems. Accessible at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM465598.pdf
5. FDA 2015: Instructions for Paper Submission of Form FDA 2541d. Accessible at http://www.fda.gov/downloads/Food/GuidanceRegulation/FoodFacilityRegistration/UCM366881.pdf

6. FDA 2015: Instructions for Paper Submission of Form FDA 2541e. Accessible at http://www.fda.gov/downloads/Food/GuidanceRegulation/FoodFacilityRegistration/UCM366882.pdf
7. FDA 2015: Instructions for Paper Submission of Form FDA 2541f. Accessible at http://www.fda.gov/downloads/Food/GuidanceRegulation/FoodFacilityRegistration/UCM366884.pdf
8. FDA 2015: Instructions for Paper Submission of Form FDA 2541g. Accessible at http://www.fda.gov/downloads/Food/GuidanceRegulation/FoodFacilityRegistration/UCM366885.pdf
9. FDA 2013: Guidance for Industry: Letter Regarding Changes to FDA's Administration of Process Filings (Forms FDA 2541a and FDA 2541c) for Acidified Foods and Low-Acid Canned Foods. Accessible at http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm378559.htm
10. FDA 2014. Form FDA 2541. Food Canning Establishment Registration. Accessible at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM076778.pdf
11. FDA. 2015. Instructions for Electronic Submission of Form FDA 2541 (Food Canning Establishment Registration) for an Acidified/Low Acid Food Canning Establishment. Accessible at http://www.fda.gov/downloads/Food/GuidanceRegulation/UCM309486.pdf
12. FDA 2015. Instructions for Paper Submission of Form FDA 2541 (Food Canning Establishment Registration) for an Acidified/Low-Acid Food Canning Establishment. Accessible at http://www.fda.gov/downloads/Food/GuidanceRegulation/FoodFacilityRegistration/UCM359392.pdf
13. FDA. Account Management. Accessible at http://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/ucm073725.htm
14. FDA. Registration of Food Facilities Step-by-Step Instructions. Accessible at http://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/ucm073706.htm