Guidance for Industry: Submitting Form FDA 2541 (Food Canning Establishment Registration) and Forms FDA 2541a and FDA 2541c (Food Process Filing Forms) to FDA in Electronic or Paper Format

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You may submit written comments regarding this guidance at any time. Submit written comments on the guidance 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 title of the guidance document.

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Guidance for Industry[1]

Submitting Form FDA 2541 (Food Canning Establishment Registration) and FDA Forms 2541a and 2541c (Food Process Filing Forms) to FDA in Electronic or Paper Format

I. Introduction

This guidance is intended for:

- Commercial processors that 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.

This guidance describes administrative procedures for submissions that are required when the products manufactured, processed, or packed by a commercial processor are subject to the registration and process filing requirements of 21 CFR 108.25(c)(2) (for AF) or 21 CFR 108.35(c)(2) (for LACF). There are two basic types of such required submissions:

- Food Canning Establishment Registration using Form FDA 2541 (Appendix 1); and
- Process filings using Forms FDA 2541a (Appendix 2) and FDA 2541c (Appendix 3).

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.

[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.

This guidance does not provide detailed instructions on how to complete electronic or paper submissions of Forms FDA 2541, 2541a, and 2541c. Such instructions are available elsewhere (See Appendices 4 through 14).

In the remainder of this guidance, "you" refers to commercial processors that manufacture, process, or pack AF or LACF and to persons who are authorized to act on behalf of such commercial processors. "We" refers to FDA.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's 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 Agency guidances means that something is suggested or recommended, but not required.

II. Background

A. 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 4) or on paper (using the instructions in Appendix 8). 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 a "facility contact person" (FCP) for the establishment being registered. We recommend that the FCP identified on Form FDA 2541 be an authorized, responsible official of the commercial processor. 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 FCP for more than one establishment.

B. 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 2541a, on the scheduled processes for each acidified food in each container size (21 CFR 108.25(c)(2)). An analogous requirement for process filing, using either Form FDA 2541a or Form FDA 2541c, applies to a commercial processor that manufactures, processes, or packs LACF (21 CFR 108.35(c)(2)). 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 2 and 3). Including the FCE number on the process filing form links your process filing to your establishment. You may submit process filing forms either electronically (using the instructions in Appendix 5) or on paper (using the instructions in Appendices 9 and 10).

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 2541a or FDA 2541c), 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 contact you and return the form to you (electronically if you submitted the form electronically or through hard copy delivery if you submitted a paper form). We will subsequently 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.

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 (Appendix 9). The SID consists of (1) the year, month, and day of the month that a process filing form is submitted, and (2) a unique sequence number to identify each form when multiple forms are submitted 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 submit a process filing, the system automatically generates a SID. When you submit a process filing using a paper form, you generate the SID yourself and include it on the paper form.

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. Some systems (including the AF/LACF system) enable the user to submit information by completing electronic forms while the user is logged into the system. Other systems (such as the Electronic Submission Gateway) enable the user to submit electronic files (such as a food additive petition) that are prepared in advance by the user (rather than completed using electronic forms while the user is logged into the system). To use the electronic FIS portal, follow the instructions in Appendix 15 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 System and Food Facility Registration (FFR)

The design of the electronic AF/LACF registration system links it to the FFR system established to implement the requirements for facility registration under section 415 of the Federal Food, Drug, and Cosmetic Act.[3] Specifically, the electronic system for submission of Form FDA 2541 is limited to facilities that are registered as food facilities under FDA's section 415 registration regulations in 21 CFR part 1, subpart H. Facilities that register in the FFR system receive an FFR number and PIN. During the section 415 registration process, or during an update to a facility's section 415 registration, you can identify your facility as an Acidified/Low-Acid Food Processor.

The electronic AF/LACF registration system in FURLS only 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 under FDA's section 415 registration regulations, but you have not yet identified yourself as an Acidified/Low-Acid Food Processor, you can update your section 415 registration information to add this information.

If you are not required to register as a food facility under FDA's section 415 registration regulations, and you want to access the electronic AF/LACF system, see section IV.A of this guidance for information about two options for doing so.

The process filing component of the electronic AF/LACF system became operational in 2005. At that time, the electronic AF/LACF system was not able to accept Form FDA 2541 electronically. FDA received your Form FDA 2541 in paper form and took steps to enable you to use the electronic AF/LACF process filing system without any link to your FFR number. As a practical matter, after your electronic access to the AF/LACF system is established, it makes no difference whether you have an FFR number. The FFR number is only needed to enable the initial electronic registration of your facility.

[3] See the requirements in 21 CFR part 1, subpart H (FDA's section 415 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.

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:

- Create an FDA Account for the electronic FIS portal by following the instructions in Appendix 15 to obtain an FDA Account ID and password.
- If you have not already done so, register as a food facility by following the instructions in Appendix 16 to obtain an FFR number and PIN. During the registration process, follow the instructions in Section 9 of Appendix 16 to identify your food facility as an Acidified/Low-Acid Food Processor.
- If you are not required to register as a food facility under FDA's section 415 registration regulations, you may either:
    - Follow the Instructions in Appendix 16 to register voluntarily and obtain an FFR number and PIN so that you can submit Form FDA 2541 electronically; or
    - Follow the Instructions in Appendix 8 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 as a food facility and have an FFR number and PIN, update your FFR registration information by following the instructions in Section 9 of Appendix 16 to identify your facility as an Acidified/Low Acid Food Processor.
- After identifying your registered food facility as an Acidified/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

Follow the instructions in Appendix 4 to register your establishment by electronic submission of Form FDA 2541. We recommend that you register your establishment electronically.

Follow the instructions in Appendix 8 to register your establishment by paper submission of Form FDA 2541.

C. FDA Receives Form FDA 2541

If you use the electronic AF/LACF system to register your establishment, the electronic registration system will automatically assign your 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 FCP. If we have questions concerning your submitted registration information, we may contact the FCP using contact information included with the registration.

If you register your establishment using a paper form, we will assign your FCE number and provide it to the FCP. If you ask us to provide you with access to the electronic AF/LACF system, we will link the electronic AF/LACF system to your FDA Account for the FIS portal so that the electronic AF/LACF system becomes available to you when you log into your FDA Account. We will inform you when it is ready for you to use.

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

The FCP may authorize one or more individuals to access the electronic AF/LACF system for a specific FCE and perform designated functions related to registration and process filing. Such individuals may be your employees or your agents.[4] The FCP will use the electronic AF/LACF system to authorize individuals to perform functions related to process filing. However, at this time the only mechanism available for the FCP to authorize another individual to perform functions related to registration is to contact us as described in section VI of this guidance. We expect that future enhancements to the electronic AF/LACF system will enable the FCP to electronically authorize other individuals to perform functions related to registration.

The FCP authorizes an individual to access the electronic AF/LACF system for a particular FCE by assigning a role to the individual as an Authorized Representative (AR) or a Read Only Access Representative (ROAR). The assigned role determines the functions the individual can perform electronically and when contacting FDA on behalf of the FCP - e.g., by email or by telephone. Table 1 shows the authorized functions that can be performed by the FCP, an AR, and a ROAR.

[4] Individuals who act as authorized agents may do so for more than one commercial processor.

Table 1. Authorized Functions Associated with Assigned Roles

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

*At this time, the only mechanism available for the FCP to authorize another individual to update registration information or to discuss registration information with FDA is to contact us as described in section VI of this guidance to ask us to add the authorization to your account.

E. Submit Process Filing Forms

Follow the instructions in Appendix 5 to submit process filing Form FDA 2541a and FDA 2541c electronically. We recommend that you submit your process filing forms electronically.

Follow the instructions in Appendices 9 and 10 to submit process filing Form FDA 2541a and FDA 2541c using paper forms.

V. Changes to Registration Information

A. Changing the Facility Contact Person

To change the FCP, contact us as described 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 4 to do so electronically or in Appendix 8 to do so by paper submission of Form FDA 2541.

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

To change the telephone number or email address for the FCP, follow the instructions in Appendix 15 to change the information in the FDA Account in the FIS electronic portal. Follow the instructions in Appendix 8 to do so by paper submission of Form FDA 2541.

D. Changing Product Information

To add or delete products from your registration information, follow the instructions in Appendix 4 to do so electronically or in Appendix 8 to do so by paper submission of Form FDA 2541.

E. Cancelling Registration

You should cancel your registration as a FCE if you cease production at the location for that FCE or transfer ownership of the establishment to another person. To cancel your registration, follow the instructions in Appendix 4 to do so electronically or contact us as described in section VI of this guidance to do so by paper submission of Form FDA 2541.

F. Relocating Your Commercial Processing Operations

If you relocate your commercial processing operations, you should cancel the registration of the previous establishment as described in section V.E of this guidance. You also should follow the instructions in Appendix 4 to register your new establishment by electronic submission of Form FDA 2541 or follow the instructions in Appendix 8 to register your new establishment by paper submission of Form FDA 2541.

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
5100 Paint Branch Parkway
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. 2003. What You Need to Know About Registration of Food Facilities.

VIII. Appendices

1. Form FDA 2541. Food Canning Establishment Registration.
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3. Form FDA 2541c. Food Process Filing for Low-Acid Aseptic Systems.
4. FDA. 2012. Instructions for Electronic Submission of Form FDA 2541 (Food Canning Establishment Registration) for an Acidified/Low Acid Food Canning Establishment.
5. FDA. 2012. Instructions for Electronic Submission of Forms FDA 2541a and 2541c (Process Filing Forms for Acidified Foods and Low-Acid Canned Foods).
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15. FDA. Account Management.
16. FDA. Registration of Food Facilities Step-by-Step Instructions.