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Draft — Not for Implementation

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

Draft Guidance

This guidance is being distributed for comment purposes only.

Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit electronic or written comments on the draft guidance within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. 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 number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document contact the Center for Food Safety and Applied Nutrition (CFSAN) at 240-402-2411.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition
January 2014

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Guidance for Industry[1]

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

This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the telephone number listed on the title page of this guidance.

I. Introduction

A. Why FDA Is Issuing This Draft Guidance

FDA ("we") is issuing this draft guidance to alert stakeholders to changes we are planning for the administrative procedures currently used by commercial processors that manufacture, process, or pack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] The Notice of Availability for this draft guidance (Ref. 1) includes instructions on how stakeholders can comment on those planned changes. The planned changes include:

- Providing the following separate process filing forms and assigning each form a unique form number:
  - Food Process Filing for Low-Acid Retorted Method (Form FDA 2541d) (Appendix 1);
  - Food Process Filing for Acidified Method (Form FDA 2541e) (Appendix 2);
  - Food Process Filing for Water Activity/Formulation Control Method (Form FDA 2541f) (Appendix 3); and
  - Food Process Filing for Low-Acid Aseptic Systems (Form FDA 2541g) (Appendix 4).

[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.

- Establishing a new "smart form" system for electronic submission of Forms FDA 2541d, 2541e, 2541f, and 2541g. After you begin entering data on the "smart form," this new electronic system will prompt you for required and optional information based on the information you already entered.
- Providing instructions for paper submission of Forms FDA 2541d, 2541e, 2541f, and 2541g (Appendices 5 through 8).
- Providing instructions for electronic submission of Forms FDA 2541d, 2541e, 2541f, and 2541g.

As of the date of this draft guidance we do not have screen shots available for the electronic versions of the new process filing forms, or instructions for submitting the new process filing forms electronically. However, the electronic versions of the new forms will request the same information as the paper forms, which are available for your reference in the Appendix. The instructions for the electronic forms will be very similar to the instructions for the paper forms, which are available for your reference in the Appendix.

If you have submitted process filing forms to FDA in the past, or if you submit such forms in the near future before the new system becomes operational, some of the changes we are making might impact the Submission Identifiers (SIDs) assigned to those submissions. We plan to send you a letter to alert you if there is this type of administrative change to your submission(s) (see Appendix 9 for our current draft of such a letter).

We will consider comments we receive, and may modify the procedures as a result of comments, before we establish the new procedures in the final version of this guidance.

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.

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, 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.

B. What Commercial Processors Should Do Until FDA Issues the Final Version of this Guidance

Many of the procedural details we describe in this draft guidance are not currently operational. This draft guidance is being issued so that you can provide us with your comments; it is not

being issued to give you information about the system that is currently active. You therefore should not refer to this draft guidance for information about submitting your process filing or registration forms to us. Instead, you should refer to our guidance dated July 2012 (Ref. 2). Once we have considered any comments and the new procedures are ready to be implemented, we will prepare the final version of this guidance and announce in the *Federal Register* that it is available. When we do so, the final version of this guidance will supersede the guidance dated July 2012, and the July 2012 guidance will be obsolete. At that point in time, the new forms and systems will become operational, and you will be able to refer to the final version of this guidance when submitting your forms to FDA.

C. What this Guidance Will Do

This guidance is intended for:

- Commercial processors who manufacture, process, or pack AF and/or LACF;
- Commercial processors who manufacture, process, or pack products that they have determined are not AF, 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.

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 process filing 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 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). [3]

D. What this Guidance Does Not Do

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

[3] As of the date of this draft guidance, these process filing forms are only available in draft form and are not yet available for your current submissions. For information about the current forms and procedures for using them, see Ref. 2 [the July 2012 guidance].

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).

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 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. 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]

[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.

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 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 (Appendices 5 through 8). 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.

C. Voluntary Registration and Process Filing

Processors who have determined that their specific food products are not acidified foods sometimes provide us with information about these products by registering using Form 2541 and then voluntarily submitting Form FDA 2541e 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 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 process filing using a paper form, and do not have an online AF/LACF account, we will respond to you using the same method that 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 design of the electronic AF/LACF registration system links it to the FFR system established to implement the requirements for food facility registration under section 415 of the Federal Food, Drug, and Cosmetic Act.[6] Specifically, the electronic system for submission of Form FDA 2541 is limited to facilities that are registered as food facilities under FDA's food facility 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 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 section 415 registration 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 options for doing so.

[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. 3) 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:

- 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 an FDA Account ID and password.
- If you have not already done so, register as a food facility by following the instructions in Appendix 14 to obtain an FFR number and PIN. During the registration process, follow the instructions in Section 9 of Appendix 14 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 food facility registration regulations, you may either:
    - Follow the Instructions in Appendix 14 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 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 as a food facility and have an FFR number and PIN, but you have not yet identified your food facility as an Acidified/Low-Acid Food Processor, update your FFR registration information by following the instructions in Section 9 of Appendix 14 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

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

If you prefer to register your 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 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 Facility Contact Person (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 process filing. Doing so is not necessary and is at the discretion of the FCP. Such individuals may be your employees or your agents.[7] The FCP can use the electronic AF/LACF system to authorize individuals to perform functions related to process filing. However, at this time only the FCP and the Super Authorized Representative (Super AR, described below) are authorized 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 Super AR, an Authorized Representative (AR), or a Read Only Access Representative (ROAR). A particular FCE can only have a single FCP and a single Super AR, but may have more than one AR and/or ROAR. The assigned role determines the functions the individual can perform electronically and when contacting FDA on behalf of the FCP. Table 1 shows the authorized functions that can be performed by the FCP, Super AR, AR, and ROAR.

[7] 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)	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
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	No
Search, print, and view a limited "Product Summary Report"	Not Applicable**	Not Applicable**	Not Applicable**	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 FCP to update registration information electronically. A Super AR who needs to discuss and/or update the registration information electronically needs to contact FDA as described in section VI of this guidance.
**The system provides this special limited search function to the ROAR. The system does not make this limited search function available to the FCP, Super AR, and AR because they have more expansive search capabilities to search, print, and view complete process filings rather than the limited "Product Summary Report".

E. Submit Process Filing Forms

As described above, process filing forms can be submitted by the FCP, 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 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 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 Facility Contact Person

To change the telephone number or email address for the FCP electronically, follow the instructions in Appendix 13 to change the information in the FDA Account in the FIS electronic portal. To change the telephone number or email address for the FCP by paper submission of Form FDA 2541, follow the instructions in Appendix 12.

D. Adding or Deleting Product Information

To add or delete products from your registration information, 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 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)). To notify us, follow the instructions in Appendix 11 to cancel your registration by electronic submission of Form FDA 2541, follow the instructions in Appendix 12 to cancel your registration by paper submission of Form FDA 2541, or contact us as described in section VI of this guidance. If you transfer ownership of the establishment to another person, you should take the above steps to inform us that you have discontinued the manufacture, processing, and packing of food at that establishment. The new owner, no later than 10 days after first engaging in the manufacture, processing, or packing of food at that establishment, must register the establishment (21 CFR 108.25(c)(1) and 108.35(c)(1)).

F. Relocating Your Commercial Processing Operations

If you relocate your commercial processing operations (i.e., you cease or discontinue the manufacture, processing, and packing of foods in one establishment and relocate some or all of those operations to a new establishment), you must notify us and cancel the registration of the previous establishment as described in section V.E of this guidance (see 21 CFR 108.25(c)(1) and 21 CFR 108.35(c)(1)). You also must register your new establishment (see 21 CFR 108.25(c)(1) and 21 CFR 108.35(c)(1)). Follow the instructions in Appendix 11 to register your new establishment by electronic submission of Form FDA 2541 or follow the instructions in Appendix 12 to register your 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 your facility on the SIDs you previously filed.

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. 2013. Notice of Availability: Draft Guidance to Industry: Submitting Form FDA 2541 (Food Canning Establishment Registration) and Forms FDA 2541d, FDA 2541e, FDA 2541g, and FDA 2541f (Food Process Filing Forms) to FDA in Electronic or Paper Format.
2. FDA 2012. Guidance to 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
3. FDA. 2012. What You Need to Know About Registration of Food Facilities.

VIII. Appendices

1. FDA 2013: Draft Form FDA 2541d. Food Process Filing for Low-Acid Retorted Method.
2. FDA 2013: Draft Form FDA 2541e. Food Process Filing for Acidified Method.
3. FDA 2013: Draft Form FDA 2541f. Food Process Filing for Water Activity/Formulation Control Method.
4. FDA 2013: Draft Form FDA 2541g. Food Process Filing for Low-Acid Aseptic Systems.
5. FDA 2013: Draft Instructions for Paper Submission of Form FDA 2541d
6. FDA 2013: Draft Instructions for Paper Submission of Form FDA 2541e
7. FDA 2013: Draft Instructions for Paper Submission of Form FDA 2541f
8. FDA 2013: Draft Instructions for Paper Submission of Form FDA 2541g
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
10. FDA 2013. Form FDA 2541. Food Canning Establishment Registration.
11. FDA. 2012. Instructions for Electronic Submission of Form FDA 2541 (Food Canning Establishment Registration) for an Acidified/Low Acid Food Canning Establishment.
12. FDA 2013. Instructions for Paper Submission of Form FDA 2541 (Food Canning Establishment Registration) for an Acidified/Low-Acid Food Canning Establishment
13. FDA. Account Management.
14. FDA. Registration of Food Facilities Step-by-Step Instructions.