Guidance for Industry: Dear Manufacturer Letter Regarding Changes to FDA's Administration of Process Filings (Forms FDA 2541a and FDA 2541c) for Acidified Foods and Low-Acid Canned Foods

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 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.

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

Guidance for Industry[1]

Dear Manufacturer Letter Regarding Changes to FDA's Administration of Process Filings (Forms FDA 2541a and FDA 2541c) for Acidified Foods and Low-Acid Canned Foods

This letter informs commercial processors of 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") of three administrative changes and one non-substantive technical change FDA is making to manage process filing forms.

Dear Industry:

The U.S. Food and Drug Administration (FDA or we) has made three administrative changes to the procedures we use to manage the process filing forms[2] submitted by commercial processors of 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") [3]. The purpose of these administrative changes is to make it easier for us to identify, and know the status of, each of your products. This letter describes these administrative changes. Most of the changes relate to process filings that you submitted using paper forms and do not impact process filings that you submitted electronically. This letter is to directly notify facilities impacted by these changes.

[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] In the past, the applicable process filing forms were designated as Forms FDA 2541a and FDA 2541c. We are revising the forms and re-naming them as Food Process Filing for Low-Acid Retorted Method (FDA 2541d), Food Process Filing for Acidified Method (FDA 2541e), Food Process Filing for Water Activity/Formulation Control Method (FDA 2541f), and Food Process Filing for Low-Acid Aseptic Systems (FDA 2541g).

[3] 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.

We also are making one non-substantive technical change to our procedures regarding information about container size on process filing forms.

Administrative Changes

The first administrative change relates to those process filings submitted using paper forms that identify several container sizes (or volumes) for a product on the same form. In the past, when we received such paper forms we assigned a single Submission Identifier (SID) to all container sizes of that product. Now, however, we will be changing some of those SIDs so that there will be a unique SID for each container size of a product. If this change affects the SIDs associated with any of your products, we are sending you the new SIDs that will be used to identify the individual products that used to be identified by a single SID. If you receive new SIDs from us, you should refer to those new SIDs in any future correspondence with FDA about these products.

The second administrative change relates to those process filings, submitted using paper forms, that you identified as "replacing" a SID on file.[4] In the past, when we received a process filing form that indicated it was replacing an existing SID, we classified the process filing being replaced as a "replaced SID" in our database system. Now, however, we are classifying a process filing being replaced as a "cancelled SID" and the new SID as a "filed SID." This change does not affect the status of any of your process filings; it only affects the terminology we assign to those process filings in our database system. We keep a "cancelled SID" in our active process filing database for 3 years and then archive the cancelled SID. Our active process filing database does not recognize an archived SID as being filed. We are applying these new procedures to both newly submitted "replacement SIDs" and to all "replaced SIDs" that are presently in our system and older than 3 years. If this change affects the terminology used to refer to any form you previously filed with us, we are notifying you about the change.

The third administrative change relates to those process filings, submitted either electronically or using paper forms, that you identified as "discontinuing" or "cancelling"[5] a SID on file. As with a "replaced SID," we are now classifying all such process filings as "cancelled," keeping them in our active process filing database for 3 years, and then archiving them. Our active process filing database does not recognize an archived SID as being filed. This change does not affect the status of any of your process filings; it only affects the terminology we assign to those process filings in our database system. We are applying these new procedures to both newly submitted discontinued or cancelled SIDs and to all discontinued or cancelled SIDs that are presently in our system and older than 3 years. If this change affects the terminology used to refer to any form you previously filed with us, we are notifying you about the change.

None of these administrative changes to our procedures affects any other information provided by your facility on your process filing forms.

Non-substantive Technical Change

[4] Section A of Form FDA 2541a and Question No. 4 of FDA 2541c allows commercial processors to indicate whether their process filing form "replaces" an existing SID.

[5] Section A of Form FDA 2541a and Question No. 4 of FDA 2541c allows commercial processors to indicate whether their process filing form "cancels" an existing SID.

The non-substantive technical change relates to those submitted process filings that identified container dimensions with a fractional value of less than one sixteenth of an inch (e.g., 405 x 301 x 014.5, where 014.5 reflects a container dimension of 14.5 sixteenths of an inch). Our system will now "round down" fractional values of less than 0.5 sixteenths of an inch and will "round up" fractional values greater than or equal to 0.5 sixteenths of an inch. For example, a container dimension that was previously represented as 014.5 would be rounded so that it is now represented as 015. This non-substantive technical change for container dimensions does not affect any other information provided by your facility on your process filing forms.

Why You Are Receiving This Letter

A check mark in one or more of the items listed below identifies the type(s) of changes that have affected process filing forms you submitted to us. Process filing forms attached to your letter provide more details about the specific changes.

☐ New SIDs for Different Container Sizes or Volumes.
☐ Replaced SID(s).
☐ Cancelled SID(s).
☐ Container Dimension Rounding.

You do not need to respond to this letter.

What to Expect

- In the future, if you use a single paper form for multiple container sizes of a product, we will contact you with new SIDs for each container size.
- If you submit process filing forms electronically, you will see that a folder previously named "Discontinued" will now be called "Cancelled."

How to Contact FDA if You Have Questions

If you have any questions, you may contact us by email directed to LACF@FDA.HHS.GOV or by letter addressed to:

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, Maryland 20740-3835
ATTENTION: LACF MIGRATION

Sincerely,

Susan J. Brecher, MBA
Team Leader, Food Processing Evaluation Team
Office of Food Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration