



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 108

[Docket No. FDA-2015-N-2819]

Emergency Permit Control Regulations; Technical Amendments

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; technical amendments.

SUMMARY: The Food and Drug Administration (FDA or we) is proposing to amend certain regulations pertaining to registration and process filings related to acidified foods and thermally processed low-acid foods packaged in hermetically sealed containers (historically referred to as "low-acid canned foods" or "LACF"). The amendments would reflect new FDA process filing form numbers and would make changes to addresses or locations where such forms can be found or must be sent. Additionally, the amendments would remove obsolete references to the effective dates that occurred years ago and update a reference to another Federal Agency.

DATES: Submit either electronic or written comments on the proposed rule by [INSERT DATE 75 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments by any of the following methods.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following way:

- Mail/Hand delivery/Courier (for paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Docket No. (FDA-2015-N-2819) for this rulemaking. All comments received may be posted without change to

<http://www.regulations.gov>, including any personal information provided. For additional information on submitting comments, see the "Comments" heading of the SUPPLEMENTARY INFORMATION section of this document.

Docket: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov> and insert the docket number(s), found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Susan Brecher, Center for Food Safety and Applied Nutrition (HFS-302), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740-3835, 240-402-1781.

SUPPLEMENTARY INFORMATION:

I. Background

Among other things, current FDA regulations at part 108 (21 CFR part 108) provide that a commercial processor, when first engaging in the manufacture, processing, or packing of

acidified foods or low-acid canned foods, must, 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 (§ 108.25(c)(1) and § 108.35(c)(1)). In addition, our regulations require the submission of process filing forms. Specifically, our regulations require that commercial processors engaged in the processing of acidified foods must, not later than 60 days after registration, and before packing any new product, provide FDA with information on the scheduled processes for each acidified food in each container size (§ 108.25(c)(2)). An analogous requirement for process filing applies to commercial processors of low-acid canned foods (§ 108.35(c)(2)). The regulations specify the specific process filing forms to be used (Forms FDA 2541a and 2541c), and also state where the forms can be obtained and where the forms should be sent.

We recently engaged in an effort to modernize our forms and to provide a means for submitting the forms using electronic "smart form" technology. This effort involved the drafting of four new draft process filing forms: Forms FDA 2541d, FDA 2541e, FDA 2541f, and FDA 2541g. (For more information about the draft new process filing forms, see "Draft 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," available at <http://www.fda.gov/FoodGuidances>.) Once completed, this effort will make it easier for firms to submit information to us and will improve the accuracy of the information submitted in the forms. In conjunction with these changes, the proposed rule would make technical amendments to § 108.25, "Acidified Foods," and § 108.35, "Thermal Processing of Low-Acid Foods Packaged in Hermetically Sealed Containers." Specifically, the

proposed rule would incorporate the new FDA form numbers. FDA hopes to finalize the new process filing forms later in 2015. By incorporating the new FDA form numbers into part 108, the proposed rule would cause the new forms to fully replace the forms currently listed in part 108 once this proposed rule becomes final and effective. At that point, FDA would no longer accept the currently-listed forms.

In addition, the proposed rule would make changes to the addresses or locations where forms can be found or must be sent. Finally, the proposed rule would remove obsolete references to dates that occurred years ago and would update the name of the Agency of the U. S. Department of Agriculture that administers the meat and poultry inspection programs under the Federal Meat Inspection Act and the Poultry Products Inspection Act.

II. Legal Authority

We are issuing this proposed rule under the Federal Food, Drug, and Cosmetic Act (the FD&C Act). Section 404(a) of the FD&C Act (21 U.S.C. 344(a)) provides that whenever the Secretary finds after investigation that the distribution in interstate commerce of any class of food may, by reason of contamination with micro-organisms during the manufacture, processing, or packing thereof in any locality, be injurious to health, and that such injurious nature cannot be adequately determined after such articles have entered interstate commerce, the Secretary then shall issue regulations providing for the issuance, to manufacturers, processors, or packers of such class of food in such locality, of permits to which shall be attached such conditions governing the manufacture, processing, or packing of such class of food, for such temporary period of time, as may be necessary to protect the public health. Under section 404 of the FD&C Act, FDA's regulations in part 108 have long required registration of food processing establishments, filing of process information, and maintenance of processing and production

records for acidified foods and low-acid canned foods. Under section 701(e) of the FD&C Act, any action for the issuance, amendment, or repeal of any regulation under section 404(a) of the FD&C Act shall be begun by a proposal made either by the Secretary on his own initiative or by petition of any interested persons, showing reasonable grounds therefor, filed with the Secretary.

III. Description of the Proposed Rule

As stated in section I, the proposed rule would make technical amendments to § 108.25, "Acidified Foods," and § 108.35, "Thermal Processing of Low-Acid Foods Packaged in Hermetically Sealed Containers." These changes would incorporate the new FDA form numbers and changes to the addresses or locations where forms can be found or must be sent. These changes would also remove obsolete references to dates that occurred years ago and would update the name of the Agency of the U. S. Department of Agriculture that administers the meat and poultry inspection programs under the Federal Meat Inspection Act and the Poultry Products Inspection Act. Specifically, the proposed rule would:

- Amend § 108.25(c)(1) and (c)(2) and § 108.35(c)(1) and (c)(2) to replace the obsolete mailing code (HFS-618) listed in those provisions with the current mailing code (HFS-303) for the FDA office identified in those provisions.
- Amend § 108.25(c)(1) and (c)(2) and § 108.35(c)(1) and (c)(2) to provide an Internet address where forms can be found or submitted. The new text would state that the forms are available on our Web site at <http://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/AcidifiedLACFRRegistration/ucm2007436.htm> and, for electronic submission, would refer to FDA's Industry Systems Web site at www.access.fda.gov.

- Amend § 108.25(c)(1) by deleting "Commercial processors presently so engaged shall register within 120 days after the effective date of this regulation." We propose to delete this sentence because the effective date occurred years ago, so the sentence is no longer necessary. We also propose to replace the sentence stating that "Foreign processors shall register within 120 days after the effective date of this regulation or before any offering of foods for import into the United States, whichever is later," with a new sentence stating that "Foreign processors shall register before any offering of foods for import into the United States." We propose to make this change because the effective date occurred years ago, so reference to the effective date is no longer necessary.
- Amend § 108.25(c)(2) by replacing "form FDA 2541a (food canning establishment process filing form for all methods except aseptic)" with "Form FDA 2541e (Food Process Filing for Acidified Method)." This change would reflect the new form number and form that FDA is introducing.
- Amend § 108.35(c)(1) by deleting the sentence stating that "Commercial processors presently so engaged shall register not later than July 13, 1973." Given the passage of time since § 108.35(c)(1) was issued, reference to the date of July 13, 1973, is no longer necessary.
- Amend § 108.35(c)(2) by replacing "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)" with a list of the following new forms: Form FDA 2541d (Food Process Filing for Low-Acid Retorted Method); Form FDA 2541f (Food Process Filing for Water Activity/Formulation Control

Method); and Form FDA 2541g (Food Process Filing for Low-Acid Aseptic Systems). These changes refer to the new form numbers and forms that FDA is introducing.

- Amend § 108.35(c)(2)(ii) by inserting "LACF Registration Coordinator (HFS-303)" before "Center for Food Safety and Applied Nutrition." This change would provide greater specificity as to the FDA office that should receive information for purposes of § 108.35(c)(2)(ii).
- Amend § 108.35(i) (which refers to "the meat and poultry inspection program of the Animal and Plant Health Inspection Service of the Department of Agriculture") by replacing "Animal and Plant Health Inspection Service" with "Food Safety Inspection Service." We are making this change because the Food Safety and Inspection Service of the U.S. Department of Agriculture now administers the meat and poultry inspection program under the Federal Meat Inspection Act and the Poultry Products Inspection Act, and not the Animal and Plant Health Inspection Service.

IV. Proposed Effective Date

We propose that any final rule resulting from this rulemaking process become effective 30 days after its date of publication in the Federal Register.

V. Economic Analysis of Impacts

We are publishing this proposed rule under the formal rulemaking process. Executive Order 12866 does not require us to analyze the costs and benefits of proposed rules that we publish under this rulemaking process.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. The proposed rule would

amend §§ 108.25 and 108.35 to delete obsolete references to long-expired effective dates, make changes to FDA addresses or locations, and reflect new process filing forms. With regard to the new process filing forms, FDA would replace references to Forms FDA 2541a and FDA 2541c with references to four new process filing forms: Forms FDA 2541d, FDA 2541e, FDA 2541f, and FDA 2541g. Some of the data entry fields on the four new process filing forms are not on current Forms FDA 2541a and FDA 2541c. The new forms add certain data entry fields to improve the efficiency of FDA's review of the process filings. For example, the new forms include data entry fields for the "food product group" (such as liquid, ready-to-eat "breakfast foods"). In addition, the new forms provide for "smart form" technology using an electronic submission system. The updated process filing portion of the electronic submission system queries the processor about the processes used to produce the food and presents only those data entry fields that are applicable. As a result, processors will no longer need to evaluate whether particular data entry fields are applicable to their products. For example, when a processor submits a process filing for a product that is processed using a low-acid retorted method with a process mode of "agitating," smart form technology would bypass questions that are not applicable to this process mode option. We estimate that the additional time it would take processors to complete the new information requested on the new forms would be offset by the time processors will save by not having to evaluate whether certain data entry fields on Form FDA 2541a or FDA 2541c are applicable to their products. Hence, we propose to certify that the rule, if finalized, will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits,

before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is \$144 million, using the most current (2014) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this proposed rule to result in any 1-year expenditure that would meet or exceed this amount.

VI. Analysis of Environmental Impact

FDA has determined, under 21 CFR 25.30(i), that this proposed rule is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VII. Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). These collections of information have been previously approved under OMB control number 0910-0037 which expires September 30, 2017.

VIII. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the proposed rule, if finalized, would not contain policies that would have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we tentatively conclude that the proposed rule does not contain policies that have federalism implications as defined in the Executive Order and, consequently, a federalism summary impact statement is not required.

IX. Additional Information Regarding Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

List of Subjects in 21 CFR Part 108

Administrative practice and procedure, Foods, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 108 be amended as follows:

PART 108--EMERGENCY PERMIT CONTROL

1. The authority citation for 21 CFR part 108 continues to read as follows:

Authority: 21 U.S.C. 342, 344, 371.

2. In §108.25, revise paragraphs (c)(1) and (c)(2) to read as follows:

§ 108.25 Acidified foods.

* * * * *

(c)(1) Registration. A commercial processor, when first engaging in the manufacture, processing, or packing of acidified foods in any State, as defined in section 201(a)(1) of the act, shall, not later than 10 days after first so engaging, register and file with the Food and Drug Administration on Form FDA 2541 (food canning establishment registration) information including, but not limited to, the name of the establishment, principal place of business, the

location of each establishment in which that processing is carried on, the processing method in terms of acidity and pH control, and a list of foods so processed in each establishment. These forms are available from the LACF Registration Coordinator (HFS-303), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or at any Food and Drug Administration district office. The completed form shall be submitted to the Center for Food Safety and Applied Nutrition (HFS-565), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. These forms also are available on the Food and Drug Administration's Web site at <http://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/AcidifiedLACFRegistration/ucm2007436.htm>. For electronic submission go to FDA's Industry Systems Web site at www.access.fda.gov. Foreign processors shall register before any offering of foods for import into the United States. Commercial processors duly registered under this section shall notify the Food and Drug Administration not later than 90 days after the commercial processor ceases or discontinues the manufacture, processing, or packing of the foods in any establishment, except that this notification shall not be required for temporary cessations due to the seasonal character of an establishment's production or by temporary conditions including, but not limited to, labor disputes, fire, or acts of God.

(2) Process filing. A commercial processor engaged in the processing of acidified foods shall, not later than 60 days after registration, and before packing any new product, provide the Food and Drug Administration information on the scheduled processes including, as necessary, conditions for heat processing and control of pH, salt, sugar, and preservative levels and source and date of the establishment of the process, for each acidified food in each container size. Filing of this information does not constitute approval of the information by the Food and Drug

Administration, and information concerning processes and other data so filed shall be regarded as trade secrets within the meaning of 21 U.S.C. 331(j) and 18 U.S.C. 1905. This information shall be submitted on Form FDA 2541e (Food Process Filing for Acidified Method). Forms are available from the LACF Registration Coordinator (HFS-303), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or at Food and Drug Administration district office. The completed form shall be submitted to the LACF Registration Coordinator (HFS-618), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. These forms also are available on the Food and Drug Administration's Web site at <http://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/AcidifiedLACFRegistration/ucm2007436.htm>. For electronic submission go to FDA's Industry Systems Web site at www.access.fda.gov.

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3. In § 108.35, revise paragraphs (c)(1), (c)(2) introductory text, (c)(2)(ii), and (i) to read as follows:

§108.35 Thermal processing of low-acid foods packaged in hermetically sealed containers.

* * * * *

(c) * * *

(1) Registration. A commercial processor when first engaging in the manufacture, processing, or packing of thermally processed low-acid foods in hermetically sealed containers in any state, as defined in section 201(a)(1) of the act, shall, not later than 10 days after first so engaging, register with the Food and Drug Administration on Form FDA 2541 (food canning

establishment registration) information including (but not limited to) his name, principal place of business, the location of each establishment in which such processing is carried on, the processing method in terms of the type of processing equipment employed, and a list of the low-acid foods so processed in each such establishment. These forms are available from the LACF Registration Coordinator (HFS-303), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or at any Food and Drug Administration district office. The completed form shall be submitted to the LACF Registration Coordinator (HFS-618), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. These forms also are available on the Food and Drug Administration's Web site at <http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/AcidifiedLow-AcidCanned/Foods/default.htm>. For electronic submission go to FDA's Industry Systems Web site at www.access.fda.gov. Commercial processors duly registered in accordance with this section shall notify the Food and Drug Administration not later than 90 days after such commercial processor ceases or discontinues the manufacture, processing, or packing of thermally processed foods in any establishment: Provided, That such notification shall not be required as to the temporary cessation necessitated by the seasonal character of the particular establishment's production or caused by temporary conditions including but not limited to strikes, lockouts, fire, or acts of God.

(2) Process filing. A commercial processor engaged in the thermal processing of low-acid foods packaged in hermetically sealed containers shall, not later than 60 days after registration and prior to the packing of a new product, provide the Food and Drug Administration information as to the scheduled processes including but not limited to the processing method,

type of retort or other thermal processing equipment employed, minimum initial temperatures, times and temperatures of processing, sterilizing value (Fo), or other equivalent scientific evidence of process adequacy, critical control factors affecting heat penetration, and source and date of the establishment of the process, for each such low-acid food in each container size:

Provided, That the filing of such information does not constitute approval of the information by the Food and Drug Administration, and that information concerning processes and other data so filed shall be regarded as trade secrets within the meaning of 21 U.S.C. 331(j) and 18 U.S.C. 1905. This information shall be submitted on the following forms as appropriate: Form FDA 2541d (Food Process Filing for Low-Acid Retorted Method), Form FDA 2541f (Food Process Filing for Water Activity/Formulation Control Method), or Form FDA 2541g (Food Process Filing for Low-Acid Aseptic Systems). These forms are available from the LACF Registration Coordinator (HFS-303), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or at any Food and Drug Administration district office. The completed form(s) shall be submitted to the LACF Registration Coordinator (HFS-303), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. These forms also are available on the Food and Drug Administration's Web site at <http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/AcidifiedLow-AcidCannedFoods/default.htm>. For electronic submission, go to FDA's Industry Systems Web site at www.access.fda.gov.

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(ii) If a packer intentionally makes a change in a previously filed scheduled process by reducing the initial temperature or retort temperature, reducing the time of processing, or

changing the product formulation, the container, or any other condition basic to the adequacy of scheduled process, he shall prior to using such changed process obtain substantiation by qualified scientific authority as to its adequacy. Such substantiation may be obtained by telephone, telegram, or other media, but must be promptly recorded, verified in writing by the authority, and contained in the packer's files for review by the Food and Drug Administration. Within 30 days after first use, the packer shall submit to the LACF Registration Coordinator (HFS-303), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740 a complete description of the modifications made and utilized, together with a copy of his file record showing prior substantiation by a qualified scientific authority as to the safety of the changed process. Any intentional change of a previously filed scheduled process or modification thereof in which the change consists solely of a higher initial temperature, a higher retort temperature, or a longer processing time, shall not be considered a change subject to this paragraph, but if that modification is thereafter to be regularly scheduled, the modified process shall be promptly filed as a scheduled process, accompanied by full information on the specified forms as provided in this paragraph.

* * * * *

(i) This section shall not apply to the commercial processing of any food processed under the continuous inspection of the meat and poultry inspection program of the Food Safety Inspection Service of the Department of Agriculture under the Federal Meat Inspection Act (34 Stat. 1256, as amended by 81 Stat. 584 (21 U.S.C. 601 et seq.)) and the Poultry Products Inspection Act (71 Stat. 441, as amended by 82 Stat. 791 (21 U.S.C. 451 et seq.)).

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Dated: September 15, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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