establishment of the Program Fraud Civil Remedies Act of 1986 serves as the base figure for the inflation calculation. Between October 1986 and October 2015, the CPI–U has increased by 215.628 percent. The post-adjustment penalty amount or range is obtained by multiplying the pre-adjustment penalty amount or range by the percent change in the CPI–U over the relevant time period, and rounding to the nearest dollar. Therefore, the new, post-adjustment penalty under the PFCRA is $5,000 × 2.15628 = $10,781.40, which rounds to $10,781. The new, post-adjustment penalties are less than 250 percent of the pre-adjustment penalties, so the limitation on the amount of the adjustment is not implicated.

III. Procedural Requirements

A. Regulatory Impact Analysis: Executive Order 12866, as Supplemented by Executive Order 13563

OPM, with the concurrence of the Office of Management and Budget (OMB), has determined that this is not a significant regulatory action under Executive Order 12866, as supplemented by Executive Order 13563. Therefore, no regulatory impact analysis is required.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) requires an agency to prepare a regulatory flexibility analysis for rules unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. The RFA applies only to rules for which an agency is required to first publish a proposed rule. See 5 U.S.C. 603(a) and 604(a). The Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 requires agencies to adjust civil penalties with an initial catch-up adjustment through an interim final rule. An interim final rule does not include first publishing a proposed rule. Thus, the RFA does not apply to this final rule.

C. Small Business Regulatory Enforcement Fairness Act (5 U.S.C. 804(2))

This rule is not a major rule under the Small Business Regulatory Enforcement Fairness Act. This rule:

(a) Does not have an annual effect on the economy of $100 million or more.

(b) Will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions.

(c) Does not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States-based enterprises to compete with foreign-based enterprises.

D. Unfunded Mandate Reform Act of 1995 (2 U.S.C. 1532)

This rule does not involve a Federal mandate that may result in the expenditure by State, local and tribal governments, in the aggregate, or by the private sector, of $100 million or more and that such rulemaking will not significantly or uniquely affect small governments.

E. E.O. 12630, Takings

This rule does not have takings implications.

F. E.O. 13132, Federalism

This rule does not have federalism implications. The rule does not 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.

G. E.O. 12988, Civil Justice Reform

This rule complies with the requirements of E.O. 12988. Specifically, this rule:

(a) Does not unduly burden the judicial system.

(b) Meets the criteria of section 3(a) requiring that all regulations be reviewed to eliminate errors and ambiguity and be written to minimize litigation; and

(c) Meets the criteria of section 3(b)(2) requiring that all regulations be written in clear language and contain clear legal standards.

H. E.O. 13175, Consultation With Indian Tribes

In accordance with Executive Order 13175, OPM has evaluated this rule and determined that it has no tribal implications.

I. Paperwork Reduction Act

This document does not contain information collection requirements subject to the Paperwork Reduction Act of 1995, Public Law 104–13.

List of Subjects in 5 CFR Part 185

Administrative practice and procedure, Claims, Fraud, Penalties.

U.S. Office of Personnel Management.

Beth F. Cobert,

Acting Director.

For the reasons set forth in the preamble, amend part 185 of title 5 of the Code of Federal Regulations as follows:

PART 185—PROGRAM FRAUD CIVIL REMEDIES: CIVIL MONETARY PENALTY INFLATION ADJUSTMENT

■ 1. The authority citation for part 185 is revised to read as follows:

Authority: 28 U.S.C. 2461 note; 31 U.S.C. 3801–3812.

§ 185.103 [Amended]

■ 2. Section 185.103 is amended as follows:

■ a. In paragraph (a) introductory text, remove ''$5,000'' and add in its place ''$10,781''.

■ b. In paragraph (f)(2), remove ''$5,000'' and add in its place ''$10,781''.

[FR Doc. 2016–17026 Filed 7–18–16; 8:45 am]

BILLING CODE 6325–48–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: Final rule; technical amendments.

SUMMARY: The Food and Drug Administration (FDA or we) is amending 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 reflect new FDA process filing form numbers, make changes to addresses or locations where such forms can be found or must be sent, remove obsolete references to the effective dates that occurred years ago, and update a reference to another Federal Agency.

DATES: This rule is effective August 18, 2016. See section VI for further information on the filing of objections. Submit either electronic or written objections and requests for a hearing by August 18, 2016.

ADDRESSES: You may submit objections and requests for a hearing as follows:

Electronic Submissions

Submit electronic objections in the following way:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the

instructions for submitting comments. Objections submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your objection will be made public, you are solely responsible for ensuring that your objection does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your objection, that information will be posted on *http://www.regulations.gov.*

• If you want to submit an objection with confidential information that you do not wish to be made available to the public, submit the objection as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

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

• For written/paper objections submitted to the Division of Dockets Management, FDA will post your objection, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2015–N–2819 for ''Emergency Permit Control Regulations; Technical Amendments.'' Received objections will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit an objection with confidential information that you do not wish to be made publicly available, submit your objections only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, 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, 5001 Campus Dr., College Park, MD 20740–3835, 240–402–1781.

SUPPLEMENTARY INFORMATION:

I. Background

Among other things, our current 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) (21 CFR 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 process filing forms: Forms FDA 2541d, FDA 2541e, FDA 2541f, and FDA 2541g. (For more information about the new process filing forms, see ''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.*) We announced that drafts of the new forms were available for public comment in a notice published in the **Federal Register** of January 14, 2014 (79 FR 2448). After considering public comment, we modified the content of the forms where appropriate and announced the availability of the finalized new process filing forms in a notice published in the **Federal Register** of October 8, 2015 (80 FR 60909).

II. Legal Authority

We are issuing this final 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 of Health and Human Services (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, our 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 (21 U.S.C. 371(e)), 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. The Secretary shall publish such proposal and shall afford all interested persons an opportunity to present their views thereon, orally or in writing. As soon as practicable thereafter, the Secretary shall by order act upon the proposal and make such order public. Except as provided in section 701(e)(2) of the FD&C Act, the order shall become effective at such time as may be specified therein, but not before the day following the last day on which objections may be filed under section 701(e)(2) of the FD&C Act.

III. The Proposed Rule

The new process filing forms described in section I 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 in the forms, in the **Federal Register** of September 22, 2015 (80 FR 57137), we proposed to make technical amendments to § 108.25, ''Acidified Foods,'' and § 108.35, ''Thermal Processing of Low-Acid Foods Packaged in Hermetically Sealed Containers.'' Specifically, we proposed to incorporate the new FDA form numbers. 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.

In addition, we proposed to make changes to the addresses or locations where forms can be found or must be sent. Finally, we proposed to remove obsolete references to dates that occurred years ago and 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.

IV. Public Comments

We received one comment on the proposed rule. This comment alerted us to the omission of the word ''and'' in the name of the Federal Agency that administers the meat and poultry inspection programs under the Federal Meat Inspection Act and the Poultry Products Inspection Act. The name of that Federal Agency is the ''Food Safety and Inspection Service,'' not the ''Food Safety Inspection Service,'' and we have revised the rule accordingly.

V. Description of the Final Rule

The final rule makes those technical amendments to § 108.25, ''Acidified Foods,'' and § 108.35, ''Thermal Processing of Low-Acid Foods Packaged in Hermetically Sealed Containers'' that we described in the proposed rule and summarized in section I of this document, with the correction noted in section IV of this document. See the amended regulatory text of §§ 108.25(c)(1) and (2) and 108.35(c)(1) and (2) and (i). The final rule will cause the new process filing forms to fully replace the forms currently listed in part 108 (*i.e.* Forms FDA 2541a and FDA 2541c).

VI. Objections

This rule is effective as shown in the **DATES** section, except as to any provisions that may be stayed by the filing of proper objections. If you will be adversely affected by one or more provisions of this regulation, you may file with the Division of Dockets Management (see **ADDRESSES**) either electronic or written objections. You must separately number each objection, and within each numbered objection you must specify with particularity the provision(s) to which you object, and the grounds for your objection. Within each numbered objection, you must specifically state whether you are requesting a hearing on the particular provision that you specify in that numbered objection. If you do not request a hearing for any particular objection, you waive the right to a hearing on that objection. If you request a hearing, your objection must include a detailed description and analysis of the specific factual information you intend to present in support of the objection in the event that a hearing is held. If you do not include such a description and analysis for any particular objection, you waive the right to a hearing on the objection.

Any objections received in response to the regulation 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.* We will publish notice of the objections that we have received or lack thereof in the **Federal Register**.

VII. Economic Analysis of Impacts

We are publishing this final rule under the formal rulemaking process. *Executive Order 12866* does not require us to analyze the costs and benefits of final 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 final rule amends §§ 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, we are replacing 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 our 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 certify that the rule 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 issuing ''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 $146 million, using the most current (2015) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

VIII. Analysis of Environmental Impact

FDA has determined, under 21 CFR 25.30(i), that this final 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.

IX. Paperwork Reduction Act of 1995

This final 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.

X. Federalism

We have analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that 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 conclude that the 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.

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, part 108 is amended as follows:

PART 108—EMERGENCY PERMIT CONTROL

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

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

■ 2. In § 108.25, revise paragraphs (c)(1) and (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, 5001 Campus Dr., 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, 5001 Campus Dr., 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, 5001 Campus Dr., 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, 5001 Campus Dr., 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.*

* * * * *

■ 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, 5001 Campus Dr., 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, 5001 Campus Dr.,

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/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, 5001 Campus Dr., 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, 5001 Campus Dr., 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/default.htm.* For electronic submission, go to FDA's Industry Systems Web site at *www.access.fda.gov.*

* * * * *

(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, 5001 Campus Dr., 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 and 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.*)).

* * * * *

Dated: July 12, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–16968 Filed 7–18–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9761]

RIN 1545–BM88

Inversions and Related Transactions; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final and temporary regulations; correcting amendment.

SUMMARY: This document contains corrections to a correction document for final and temporary regulations (TD 9761) that was published in the **Federal Register** on June 23, 2016 (81 FR 40810).

DATES: This correction is effective on July 19, 2016 and applicable on June 23, 2016.

FOR FURTHER INFORMATION CONTACT: Rose E. Jenkins at (202) 317–6934 (not a toll free number).

SUPPLEMENTARY INFORMATION:

Background

The final and temporary regulations (TD 9761) that are the subject of this correction are under sections 304, 367, 956, 7701(l), and 7874 of the Internal Revenue Code.

Correction of Publication

In correcting amendment FR Doc. 2016–14649, published in the issue of Thursday, June 23, 2016 (81 FR 40810), make the following correction:

On page 40811, in the first column, remove amendatory instruction 6.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Accordingly, 26 CFR part 1 is corrected by making the following correcting amendments:

PART 1—INCOME TAXES

■ **Paragraph 1.** The authority citation for part 1 continues to read in part as follows: