data concerning patient visits to hospital outpatient and emergency departments. NAMCS and NHAMCS are the principal sources of data on ambulatory care provided in the United States.

There is no cost to the respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hrs.)	Total burden (in hrs.)
Office-based physicians	Physician Induction Interview (NAMCS–1)	2,590	1	45/60	1,943
	Patient Record form (NAMCS–30) (Physician abstracts).	259	30	14/60	1,813
	Prepare and transmit EHR (MU On-Boarding)	130	1	1	130
	Pulling, refiling medical record forms (FR abstracts).	2,201	30	1/60	1,101
Community Health Centers.	Induction Interview—service delivery site (NAMCS–201).	104	1	30/60	52
	Induction Interview—Providers (NAMCS–1)	234	1	30/60	117
	Patient Record form (NAMCS–30) (Provider abstracts).	23	30	14/60	161
	Pulling, refiling medical record forms (FR abstracts).	211	30	1/60	106
Reabstraction study	Pulling, refiling medical record forms abstracts)	72	10	1/60	12
Total					5,435

Leroy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2015–25648 Filed 10–7–15; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–1622]

Submitting Food Canning Establishment Registration Form and Food Process Filing Forms to the Food and Drug Administration in Electronic or Paper Format: Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a guidance entitled ''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: Guidance for Industry.'' This guidance describes the administrative procedures to be 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''). These changes include new registration and food process filing forms and a new ''smart form'' system for electronic submission of the process filing forms. Registration and process filing are required by the AF and LACF provisions of our regulations. This guidance also provides general information about how to use FDA's systems for electronic submission of the applicable forms. In addition, this guidance describes administrative procedures for voluntary registration and voluntary submissions when a commercial processor has determined that its product is not an acidified food or a low-acid canned food, and is therefore not subject to our regulations for AF and LACF. Further, this guidance describes a voluntary process whereby, upon request, we review data and other information that relate to a new processing method or new equipment.

DATES: Submit either electronic or written comments on FDA guidances at any time.

ADDRESSES: You may submit comments as follows:

Electronic Submissions: Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment 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 comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment 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 comments submitted to the Division of Dockets Management, FDA will post your comment, 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–2013–D–1622 for Submitting Food Canning Establishment Registration Form and Food Process Filing Forms to the Food and Drug Administration in Electronic or Paper Format: Guidance for Industry; Availability. Received comments 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 a comment with confidential information that you do not wish to be made publicly available, submit your comments 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.

Submit written requests for single copies of the guidance entitled ''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: Guidance for Industry'' to Office of Food Safety, Center for Food Safety and Applied Nutrition (HFS–HFS–302), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

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, 240–402–1781.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a guidance for industry entitled ''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: Guidance for Industry.'' This guidance is being issued consistent with our good guidance practices regulation (21 CFR 10.115). The guidance represents our 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. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

This guidance supersedes the previous guidance entitled ''Guidance for Industry: Submitting Form FDA 2541 (Food Canning Establishment Registration) and Forms FDA 2541a and FDA 2541c (Food Process Filing Forms) to FDA in Electronic or Paper Format.'' Among other things, it provides guidance on administrative procedures related to new process filing forms (Forms FDA 2541d, FDA 2541e, FDA 2541f, and FDA 2541g) that will replace the current process filing forms (Forms FDA 2541a and 2541c). The process filing regulations in 21 CFR 108.25(c)(2) and 108.35(c)(2) currently specify 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 these regulations to specify the new form numbers, and to provide information about how to access the online system for electronic submission of these forms, as soon as possible.

This guidance describes: (1) Administrative procedures relating to the registration requirements of 21 CFR 108.25(c)(1) (for AF) using Form FDA 2541 in both electronic and paper format; (2) administrative procedures relating to the registration requirements of § 108.35(c)(1) (for LACF) using Form FDA 2541 in both electronic and paper format; (3) administrative procedures relating to the process filing requirements of § 108.25(c)(2) (for AF) using Form FDA 2541e in both electronic and paper format; (4) administrative procedures relating to the process filing requirements of § 108.35(c)(2) (for LACF) using Forms FDA 2541d, FDA 2541f, and FDA 2541g in both electronic and paper format; (5) administrative procedures for voluntary registration and voluntary process filing submissions when a commercial processor has determined that its product is not an acidified food (or a low-acid canned food), and is therefore not subject to 21 CFR part 113, 21 CFR part 114, or part 108; and (6) a voluntary process whereby, upon request, we review data and other information that relate to a new processing method or new equipment.

In the **Federal Register** of January 14, 2014 (79 FR 2448), we made available a draft guidance entitled ''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'' and gave interested parties an opportunity to submit comments by March 17, 2014, for us to consider before beginning work on the final version of the guidance. We received a few comments on the draft guidance, largely directed to the specific content of the forms discussed in the guidance rather than to the procedures described in the guidance, and have not made any modifications to the final guidance as a result of these comments. We have, however, modified the content of the forms where appropriate. We have deleted information, which we had included in the draft guidance, explaining how the draft guidance would eventually supersede previous administrative guidance associated with previous editions of the forms, which are now obsolete. We also have modified the Appendix of the final guidance to include additional resources—*e.g.,* instructions for submitting process filing forms electronically. The guidance announced in this notice finalizes the draft guidance dated January 2014.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information 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). The collections of information in parts 108, 113, and 114 have been approved under OMB control number 0910–0037. The collections of information related to 21 CFR 1.230 through 1.233 and section 415 of the Federal Food, Drug, and Cosmetic Act

(21 U.S.C. 350d) have been approved under OMB control number 0910–0502.

III. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/FoodGuidances, http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocuments RegulatoryInformation/AcidifiedLACF/default.htm* or *http://www.regulations.gov.* Use the FDA Web site listed in the previous sentence to find the most current version of the guidance.

Dated: October 5, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–25642 Filed 10–7–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0294]

Agency Information Collection Activities; Proposed Collection; Comment Request; Food Contact Substance Notification Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the collection of information associated with the Food Contact Substance Notification Program.

DATES: Submit either electronic or written comments on the collection of information by December 7, 2015.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment 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 comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment 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 comments submitted to the Division of Dockets Management, FDA will post your comment, 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–2012–N–0294 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Food Contact Substance Notification Program.'' Received comments 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 a comment with confidential information that you do not wish to be made publicly available, submit your comments 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: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, we are publishing this notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, we invite comments on these topics: (1) Whether the proposed collection of information