FDA's normal procedures for timely payment of the PDUFA fee for the human drug application.

Payment must be made in U.S. currency by electronic check, check, bank draft, wire transfer, credit card, or U.S. postal money order payable to the order of the Food and Drug Administration. The preferred payment method is online using electronic check (Automated Clearing House (ACH) also known as eCheck). Secure electronic payments can be submitted using the User Fees Payment Portal at *https://userfees.fda.gov/pay* (*Note:* Only full payments are accepted. No partial payments can be made online). Once you search for your invoice, select ''Pay Now'' to be redirected to *Pay.gov*. Note that electronic payment options are based on the balance due. Payment by credit card is available for balances that are less than $25,000. If the balance exceeds this amount, only the ACH option is available. Payments must be made using U.S bank accounts as well as U.S. credit cards.

If paying with a paper check the invoice number should be included on the check, followed by the words ''Rare Pediatric Disease Priority Review.'' All paper checks must be in U.S. currency from a U.S. bank made payable and mailed to: Food and Drug Administration, P.O. Box 979107, St. Louis, MO 63197–9000.

If checks are sent by a courier that requests a street address, the courier can deliver the checks to: U.S. Bank, Attention: Government Lockbox 979107, 1005 Convention Plaza, St. Louis, MO 63101. (*Note:* This U.S. Bank address is for courier delivery only. If you have any questions concerning courier delivery contact the U.S. Bank at 314–418–4013. This telephone number is only for questions about courier delivery). The FDA post office box number (P.O. Box 979107) must be written on the check. If needed, FDA's tax identification number is 53–0196965.

If paying by wire transfer, please reference your invoice number when completing your transfer. The originating financial institution may charge a wire transfer fee. If the financial institution charges a wire transfer fee it is required to add that amount to the payment to ensure that the invoice is paid in full. The account information is as follows: U.S. Dept. of Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Account Number: 75060099, Routing Number: 021030004, SWIFT: FRNYUS33, Beneficiary: FDA, 8455 Colesville Rd., 14th Floor, Silver Spring, MD 20993–0002.

V. Reference

The following reference is on display in the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Ridley, D.B., H.G. Grabowski, and J.L. Moe, ''Developing Drugs for Developing Countries,'' *Health Affairs,* vol. 25, no. 2, pp. 313–324, 2006.

Dated: September 22, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–20798 Filed 9–27–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1119]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Food Canning Establishment Registration, Process Filing, and Recordkeeping for Acidified Foods and Thermally Processed Low-Acid Foods in Hermetically Sealed Containers

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by October 30, 2017.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0037. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

I. Background

Food Canning Establishment Registration, Process Filing, and Recordkeeping for Acidified Foods and Thermally Processed Low-Acid Foods in Hermetically Sealed Containers 21 CFR 108.25 and 108.35, and Parts 113 and 114

OMB Control Number 0910–0037—Extension

Section 402 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 342) deems a food to be adulterated, in part, if the food bears or contains any poisonous or deleterious substance that may render it injurious to health. Section 301(a) of the FD&C Act (21 U.S.C. 331(a)) prohibits the introduction or delivery for introduction into interstate commerce of adulterated food. Under section 404 of the FD&C Act (21 U.S.C. 344), our regulations require registration of food processing establishments, filing of process or other data, and maintenance of processing and production records for acidified foods and thermally processed low-acid foods in hermetically sealed containers. These requirements are intended to ensure safe manufacturing, processing, and packing procedures, and to permit us to verify that these procedures are being followed. Improperly processed low-acid foods present life-threatening hazards if contaminated with foodborne microorganisms, especially *Clostridium botulinum.* The spores of *C. botulinum* need to be destroyed or inhibited to avoid production of the deadly toxin that causes botulism. This is accomplished with good manufacturing procedures, which must include the use of adequate heat processes or other means of preservation.

To protect the public health, our regulations require that each firm that manufactures, processes, or packs acidified foods or thermally processed low-acid foods in hermetically sealed containers for introduction into interstate commerce register the establishment with us using Form FDA 2541 (§§ 108.25(c)(1) and 108.35(c)(2) (21 CFR 108.25(c)(1) and 108.35(c)(2)). In addition to registering the plant, each firm is required to provide data on the processes used to produce these foods, using Forms FDA 2541d, FDA 2541e,

and FDA 2541f for all methods except aseptic processing, or Form FDA 2541g for aseptic processing of low-acid foods in hermetically sealed containers (§§ 108.25(c)(2) and 108.35(c)(2)). Plant registration and process filing may be accomplished simultaneously. Process data must be filed prior to packing any new product, and operating processes and procedures must be posted near the processing equipment or made available to the operator (21 CFR 113.87(a)).

Regulations in parts 108, 113, and 114 (21 CFR parts 108, 113, and 114) require firms to maintain records showing adherence to the substantive requirements of the regulations. These records must be made available to FDA on request. Firms also must document corrective actions when process controls and procedures do not fall within specified limits (§§ 113.89, 114.89, and 114.100(c)); to report any instance of potential health-endangering spoilage, process deviation, or contamination with microorganisms where any lot of the food has entered distribution in commerce (§§ 108.25(d) and 108.35(d) and (e)); and to develop and keep on file plans for recalling products that may endanger the public health (§§ 108.25(e) and 108.35(f)). To permit lots to be traced after distribution, acidified foods and thermally processed low-acid foods in hermetically sealed containers must be marked with an identifying code (§ 113.60(c)) (thermally processed foods) and § 114.80(b) (acidified foods)).

The records of processing information are periodically reviewed during factory inspections by FDA to verify fulfillment of the requirements in parts 113 or 114. Scheduled thermal processes are examined and reviewed to determine their adequacy to protect public health. In the event of a public health emergency, records are used to pinpoint potentially hazardous foods rapidly and thus limit recall activity to affected lots.

As described in our regulations, processors may obtain the paper versions of Forms FDA 2541, FDA 2541d, FDA 2541e, FDA 2541f, and FDA 2541g by contacting us at a particular address or by visiting *https://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/AcidifiedLACFRegistration/ucm2007436.htm.* Processors mail completed paper forms to us. However, processors who are subject to § 108.25, § 108.35, or both, have an option to submit Forms FDA 2541, FDA 2541d, FDA 2541e, FDA 2541f, and FDA 2541g electronically (Ref. 1).

Although we encourage commercial processors to use the electronic submission system for plant registration and process filing, we will continue to make paper-based forms available. To standardize the burden associated with process filing, regardless of whether the process filing is submitted electronically or using a paper form, we are offering the public the opportunity to use four forms, each of which pertains to a specific type of commercial processing and is available both on the electronic submission system and as a paper-based form. The electronic submission system and paper-based form ''mirror'' each other to the extent practicable. The four process filing forms are as follows:

- Form FDA 2541d (Food Process Filing for Low-Acid Retorted Method) (Ref. 2);
- Form FDA 2541e (Food Process Filing for Acidified Method) (Ref. 3);
- Form FDA 2541f (Food Process Filing for Water Activity/Formulation Control Method) (Ref. 4); and
- Form FDA 2541g (Food Process Filing for Low-Acid Aseptic Systems) (Ref. 5).

At this time, the paper-based versions of the four forms and their instructions are all available for review as references to this document (Refs. 2 through 5) or at *https://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/AcidifiedLACFRegistration/ucm2007436.htm.*

Description of Respondents: The respondents to this information collection are commercial processors and packers of acidified foods and thermally processed low-acid foods in hermetically sealed containers.

In the **Federal Register** of June 20, 2017 (82 FR 28069), FDA published a 60-day notice requesting public comment on the proposed collection of information. While no comments were submitted to the docket, it was noted that the notice included an inadvertent reference to outdated forms. We regret this oversight and have made appropriate corrections in this notice. The forms developed in support of the information collection are intended to minimize burden on respondents while maximizing utility for FDA, and thus we are continuously open to suggestions on how they might be improved.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	FDA form number	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (minutes)	Total hours
§§ 108.25(c)(1) and 108.35(c)(2); Food canning establishment registration	2541	645	1	645	0.17 (10)	110
§ 108.25(c)(2); Food process filing for acidified method	2541e	726	11	7,986	0.333 (20)	2,659
§ 108.35(c)(2); Food process filing for low-acid retorted method	2541d	336	12	4,032	0.333 (20)	1,343
§ 108.35(c)(2); Food process filing for water activity/formulation control method	2541f	37	6	222	0.333 (20)	74
§ 108.35(c)(2); Food process filing for low-acid aseptic systems	2541g	42	22	924	0.75 (45)	693

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

21 CFR section	FDA form number	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (minutes)	Total hours
§§ 108.25(d) and 108.35(d) and (e); Report of any instance of potential health endangering spoilage, process deviation, or contamination with microorganisms where any lot of the food has entered distribution in commerce	N/A	1	1	1	4	4
Total					4,883	

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA bases its estimate of the number of respondents in table 1 on registrations, process filings, and reports received over the past 3 years. The hours per response reporting estimates are based on our experience with similar programs and information received from industry. The reporting burden for §§ 108.25(d) and 108.35(d) and (e) is minimal because notification of spoilage, process deviation, or contamination of product in distribution occurs less than once a year. Most firms discover these problems before the product is distributed, and are therefore not required to report the occurrence. We estimate that we will receive one report annually under §§ 108.25(d) and 108.35(d) and (e). The report is expected to take 4 hours per response, for a total of 4 hours.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR part	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
108, 113, and 114	10,392	1	10,392	250	2,598,000

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA bases its estimate of 10,392 recordkeepers in table 2 on its records of the number of registered firms, excluding firms that were inactive or out of business, yet still registered. To avoid double-counting, we have not included estimates for §§ 108.25(g), 108.35(c)(2)(ii), and 108.35(h) because they merely cross-reference recordkeeping requirements contained in parts 113 and 114 and have been accounted for in the recordkeeping burden estimate. We estimate that 10,392 firms will expend approximately 250 hours per year to fully satisfy the recordkeeping requirements in parts 108, 113 and 114, for a total of 2,598,000 hours.

Finally, our regulations require that processors mark thermally processed low-acid foods in hermetically sealed containers (§ 113.60(c)) and acidified foods (§ 114.80(b)) with an identifying code to permit lots to be traced after distribution. We seek OMB approval of the third-party disclosure requirements in §§ 113.60(c) and 114.80(b). However, we have not included a separate table to report the estimated burden of these regulations. No burden has been estimated for the third-party disclosure requirements in §§ 113.60(c) and 114.80(b) because the coding process is done as a usual and customary part of normal business activities. Coding is a business practice in foods for liability purposes, inventory control, and process control in the event of a problem. Under 5 CFR 1320.3(b)(2), the time, effort, and financial resources necessary to comply with a collection of information are excluded from the burden estimate if the reporting, recordkeeping, or disclosure activities needed to comply are usual and customary because they would occur in the normal course of activities. The burden for this information collection has not changed since the last OMB approval.

II. References

The following references are on display in the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *https://www.regulations.gov/*. FDA has verified the Web site addresses as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

1. FDA 2016. ''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 *https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/AcidifiedLACF/ucm309376.htm.*
2. Form FDA 2541d. Food Process Filing for Low-Acid Retorted Method. Available at *https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM465591.pdf.*
3. Form FDA 2541e. Food Process Filing for Acidified Method. Available at *https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM465593.pdf.*
4. Form FDA 2541f. Food Process Filing for Water Activity/Formulation Control Method. Available at *https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM465595.pdf.*
5. Form FDA 2541g. Food Process Filing for Low-Acid Aseptic Systems. Available at *https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM465598.pdf.*

Dated: September 22, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–20791 Filed 9–27–17; 8:45 am]

BILLING CODE 4164–01–P