TABLE 5—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Submission of ''Voluntary National Retail Food Regulatory Program Standards FDA National Registry Report''.	500	1	500	0.1 (6 minutes)	50
Request for documentation of successful completion of staff training.	500	3	1,500	0.1 (6 minutes)	150
Total	.....	.....	.....	.....	200

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

FDA bases its estimates of the number of respondents and the hours per response on its experience with the Program Standards. As explained previously in this document, FDA estimates that no more than 500 regulatory jurisdictions will participate in the Program Standards in any given year. FDA estimates a total of 6 minutes annually for each enrolled jurisdiction to complete the form. FDA bases its estimate on the small number of data elements on the form and the ease of availability of the information. FDA estimates that, annually, 500 regulatory jurisdictions will submit one Form FDA 3598 for a total of 500 annual responses. Each submission is estimated to take 0.1 hour (or 6 minutes) per response for a total of 50 hours. In addition, FDA estimates that, annually, 500 regulatory jurisdictions will submit three requests for documentation of successful completion of staff training using the CFP Training Plan and Log for a total of 1,500 annual responses. Each submission is estimated to take 0.1 hour (or 6 minutes) per response for a total of 150 hours. Thus, the total reporting burden for this information collection is 200 hours.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: February 10, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–03464 Filed 2–20–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–1066]

Agency Information Collection Activities; Proposed Collection; Comment Request; Annual Reporting for Custom Device Exemption

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (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 information collection associated with the annual reporting for custom devices.

DATES: Submit either electronic or written comments on the collection of information by April 21, 2020.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before April 21, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of April 21, 2020. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://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 *https://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):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, 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–2017–N–1066 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Annual Reporting for Custom Device Exemption.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as

''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff 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 *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. 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: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), 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, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Annual Reporting for Custom Device Exemption

OMB Control Number 0910–0767—Extension

The custom device exemption is set forth at section 520(b)(2)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360j(b)(2)(B)). A custom device is in a narrow category of device that, by virtue of the rarity of the patient's medical condition or physician's special need the device is designed to treat, it would be impractical for the device to comply with premarket review regulations and performance standards.

The Food and Drug Administration Safety and Innovation Act (FDASIA) implemented changes to the custom device exemption contained in section 520(b) of the FD&C Act. The new provision amended the existing custom device exemption and introduced new concepts and procedures for custom devices, such as:

• Devices created or modified to comply with the order of an individual physician or dentist;

• the potential for multiple units of a device type (limited to no more than five units per year) qualifying for the custom device exemption; and

• annual reporting requirements by the manufacturer to FDA about devices manufactured and distributed under section 520(b) of the FD&C Act.

Under FDASIA, ''devices'' that qualify for the custom device exemption contained in section 520(b) of the FD&C Act were clarified to include no more than ''five units per year of a particular device type'' that otherwise meet all the requirements necessary to qualify for the custom device exemption.

In the **Federal Register** of September 24, 2014 (79 FR 57112), FDA announced the availability of the guidance entitled ''Custom Device Exemption.'' FDA has developed this document to provide guidance to industry and FDA staff about implementation of the custom device exemption contained in the FD&C Act. The intent of the guidance is to define terms used in the custom device exemption, explain how to interpret the ''five units per year of a particular device type'' language contained in the FD&C Act, describe information that FDA proposes manufacturers should submit in the custom device annual report, and provide recommendations on how to submit an annual report for devices distributed under the custom device exemption. FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Annual reporting for custom devices	34	1	34	40	1,360

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

Our estimated burden for the information collection reflects an overall increase of 40 hours and a corresponding increase of one response/record. We attribute this adjustment to an increase in the number of submissions we received over the last few years.

Dated: February 12, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–03459 Filed 2–20–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–6083]

Hospira, Inc., et al.; Withdrawal of Approval of 15 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of 15 abbreviated new drug applications (ANDAs) from multiple applicants. The applicants notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of March 23, 2020.

FOR FURTHER INFORMATION CONTACT: Martha Nguyen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1676, Silver Spring, MD 20993–0002, 240–402–6980, *Martha.Nguyen@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The applicants listed in the table have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process described in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

Application No.	Drug	Applicant
ANDA 040372	Promethazine Hydrochloride (HCl) Injection, 25 milligrams (mg)/milliliter (mL) and 50 mg/mL.	Hospira, Inc., 275 North Field Dr., Bldg. H1, Lake Forest, IL 60045.
ANDA 062791	Cephalexin Capsules, Equivalent to (EQ) 250 mg base and 500 mg base.	Sun Pharmaceutical Industries, Inc., 2 Independence Way, Princeton, NJ 08540.
ANDA 065226	Cefazolin Sodium for Injection, EQ 500 mg base/vial and EQ 1 gram (g) base/vial.	Hospira, Inc.
ANDA 065244	Cefazolin Sodium for Injection, EQ 1 g base/vial	Do.
ANDA 065375	Cefotetan Disodium for Injection, EQ 10 g base/vial	Fresenius Kabi USA, LLC., Three Corporate Dr., Lake Zurich, IL 60047.
ANDA 065386	Piperacillin Sodium and Tazobactam Sodium for Injection, EQ 2 g base/vial; EQ 250 mg base/vial, EQ 3 g base/vial; EQ 375 mg base/vial, EQ 4 g base/vial; EQ 500 mg base/vial.	Hospira, Inc.
ANDA 065446	Piperacillin Sodium and Tazobactam Sodium for Injection, EQ 36 g base/vial; EQ 4.5 g base/vial.	Do.
ANDA 075955	Amiodarone HCl Injection, 50 mg/mL	Do.
ANDA 076124	Ranitidine HCl Syrup, EQ 15 mg base/mL	Actavis Mid Atlantic, LLC., Subsidiary of Teva Pharmaceuticals USA, Inc., 400 Interpace Pkwy., Morris Corporate Center III, Bldg. A, Third Floor, Parsippany, NJ 07054.
ANDA 076722	Ketorolac Tromethamine Injection, 15 mg/mL, 30 mg/mL, and 60 mg/mL.	INC Research, LLC., 4800 Falls of Neuse Rd., Suite 600, Raleigh, NC 27609.
ANDA 080700	Chlorpheniramine Maleate Tablets, 4 mg	Sun Pharmaceutical Industries, Inc.
ANDA 083201	Hydrocortisone Lotion, 1%	Crown Laboratories, Inc., 349 Lafe Cox Dr., Johnson City, TN 37604.
ANDA 201654	Cefazolin Sodium for Injection, EQ 1 g base/vial	Hospira, Inc.
ANDA 203950	Oxacillin Sodium for Injection, EQ 1 g base/vial and EQ 2 g base/vial.	Do.
ANDA 207731	Nystatin and Triamcinolone Acetonide Ointment, 100,000 units/g; 0.1%.	Crown Laboratories, Inc.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of March 23, 2020. Approval of each entire application is withdrawn, including any strengths or products inadvertently missing from the table. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in the table that are in inventory on March 23, 2020 may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: February 18, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–03512 Filed 2–20–20; 8:45 am]

BILLING CODE 4164–01–P