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

Activity/21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Acceptance activities—820.80(a)–(e)	24,738	1	24,738	5	123,690
Acceptance status—820.86	24,738	1	24,738	1	24,738
Control of nonconforming product—820.90(a)	24,738	1	24,738	5	123,690
Nonconforming product review/disposition procedures and rework procedures—820.90(b)(1)–(b)(2)	24,738	1	24,738	5	123,690
Procedures for corrective/preventive actions—820.100(a)(1)–(a)(7)	24,738	1	24,738	12	296,856
Corrective/preventive activities—820.100(b)	24,738	1	24,738	1	24,738
Labeling procedures—820.120(b)	24,738	1	24,738	1	24,738
Labeling documentation—820.120(d)	24,738	1	24,738	1	24,738
Device packaging—820.130	24,738	1	24,738	1	24,738
Handling—820.140	24,738	1	24,738	6	148,428
Storage—820.150(a) and (b)	24,738	1	24,738	6	148,428
Distribution procedures and records—820.160(a) and (b)	24,738	1	24,738	1	24,738
Installation—820.170	24,738	1	24,738	2	49,476
Record retention period—820.180(b) and (c)	24,738	1	24,738	2	49,476
Device master record—820.181	24,738	1	24,738	1	24,738
Device history record—820.184	24,738	1	24,738	1	24,738
Quality system record—820.186	24,738	1	24,738	1	24,738
Complaint files—820.198(a), (c), and (g)	24,738	1	24,738	5	123,690
Servicing procedures and reports—820.200(a) and (d)	24,738	1	24,738	3	74,214
Statistical techniques procedures and sampling plans—820.250	24,738	1	24,738	1	24,738
Total					8,608,824

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

Dated: November 28, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–29028 Filed 12–2–16; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–0117]

Agency Information Collection Activities; Proposed Collection; Comment Request; Providing Information About Pediatric Uses of Medical Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) 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 information collection regarding ''Providing Information About Pediatric Uses of Medical Devices Under Section 515A of the Federal Food, Drug, and Cosmetic Act.''

DATES: Submit either electronic or written comments on the collection of information by February 3, 2017.

ADDRESSES: You may submit comments as follows:

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):* 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–0117 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Providing Information About Pediatric Uses of Medical Devices.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://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 *https://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 *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 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, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, *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, 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.

Providing Information About Pediatric Uses of Medical Devices Under Section 515A of the Federal Food, Drug, and Cosmetic Act—OMB Control Number 0910–0762—Extension

The guidance document entitled ''Providing Information About Pediatric Uses of Medical Devices—Guidance for Industry and Food and Drug Administration Staff'' suggests that applicants who submit certain medical device applications include, if readily available, pediatric use information for diseases or conditions that the device is being used to treat, diagnose, or cure that are outside the device's approved or proposed indications for use, as well as an estimate of the number of pediatric patients with such diseases or conditions. The information submitted will allow FDA to identify pediatric uses of devices outside their approved or proposed indication for use to determine areas where further pediatric device development could be useful. This recommendation applies to applicants who submit the following applications: (1) Any request for a humanitarian device exemption submitted under section 520(m) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360j(m)); (2) any premarket approval application (PMA) or supplement to a PMA submitted under section 515 of the FD&C Act (21 U.S.C. 360e); and (3) any product development protocol submitted under section 515 of the FD&C Act.

Respondents are permitted to submit information relating to uses of the device outside the approved or proposed indication if such uses are described or acknowledged in acceptable sources of readily available information. We estimate that 20 percent of respondents submitting information required by section 515A of the FD&C Act will choose to submit this information and that it will take 30 minutes for them to do so.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Description	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Uses outside approved indication	148	1	148	0.5 (30 minutes)	74

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

Dated: November 29, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–29105 Filed 12–2–16; 8:45 am]

BILLING CODE 4164–01–P