DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–3995]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Devices; Pediatric Uses of Devices; Requirement for Submission of Information on Pediatric Subpopulations That Suffer From a Disease or Condition That a Device Is Intended To Treat, Diagnose, or Cure

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) 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 April 14, 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 0910–0748. Also include the FDA docket number found in brackets in the heading of this document.

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

Medical Devices; Pediatric Uses of Devices; Requirement for Submission of Information on Pediatric Subpopulations That Suffer From a Disease or Condition That a Device Is Intended To Treat, Diagnose, or Cure

OMB Control Number 0910–0748—Extension

Section 515A(a) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360e–1) requires applicants who submit certain medical device applications to include readily available information providing a description of any pediatric subpopulations that suffer from the disease or condition that the device is intended to treat, diagnose, or cure, and the number of affected pediatric patients. The information submitted will allow FDA to track the number of approved devices for which there is a pediatric subpopulation that suffers from the disease or condition that the device is intended to treat, diagnose, or cure and the review time for each such device application.

These requirements apply to applicants who submit humanitarian device exemption requests (HDEs), premarket approval applications (PMAs) or PMA supplements, or a product development protocol (PDP).

FDA expects to receive approximately 45 original PMA/PDP/HDE applications each year, 5 of which FDA expects to be HDEs. This estimate is based on the average of FDA's receipt of new PMA applications. The Agency estimates that 10 of the estimated 40 original PMA submissions will fail to provide the required pediatric use information and their sponsors will therefore be required to submit PMA amendments. The Agency also expects to receive approximately 700 supplements that will include the pediatric use information required by section 515A(a) of the FD&C Act and part 814 (21 CFR part 814).

All that is required is to gather, organize, and submit information that is readily available, using any approach that meets the requirements of section 515A(a) of the FD&C Act and part 814. We believe that because the applicant is required to organize and submit only readily available information, no more than 8 hours will be required to comply. Furthermore, because supplements may include readily available information on pediatric populations by referencing a previous submission, FDA estimates the average time to obtain and submit the required information in a supplement to be 2 hours. FDA estimates that the total estimated burden is 1,760 hours.

In the **Federal Register** of December 16, 2016 (81 FR 91181), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity/21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Pediatric information in an original PMA or PDP—814.20(b)(13)	30	1	30	8	240
Pediatric information in a PMA amendment—814.37(b)(2)	10	1	10	8	80
Pediatric information in a PMA supplement—814.39(c)(2)	700	1	700	2	1,400
Pediatric information in an HDE—814.104(b)(6)	5	1	5	8	40
Total					1,760

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

Dated: March 9, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–05096 Filed 3–14–17; 8:45 am]

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