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 Under Section 515A of the Federal Food, Drug, and Cosmetic Act—21 CFR 814

OMB Control Number 0910–0748—Extension

Section 515A(a) of the Food, Drug, and Cosmetic Act (21 U.S.C. 360e–1) (FD&C Act) 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 amendments or supplements, or a product development protocol (PDP).

FDA expects to receive approximately 47 original PMA/PDP/HDE applications each year, 1 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 11 of the estimated 47 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 928 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 is a supplement to be 2 hours. FDA estimates that the total estimated burden is 2,392 hours.

Additionally, the guidance document entitled ''Providing Information About Pediatric Uses of Medical Devices—Guidance for Industry and Food and Drug Administration Staff'' describes how to compile and submit the readily available pediatric use information required under section 515A(a) 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(a) 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:

Activity	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)	11	1	11	8	88
Pediatric information in a PMA amendment—814.37(b)(2)	5	1	5	8	40
Pediatric information in a PMA supplement—814.39(c)(2)(i)	928	1	928	2	1,856
Pediatric information in an HDE—814.104(b)(6)	1	1	1	8	8
Pediatric information for uses outside approved indication	800	1	800	.5	400
Total					2,392

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

Our estimated burden and corresponding responses reflect the requirements under section 515A(a) of the FD&C Act, in addition to the submission of data related to pediatric uses outside an approved indication, as described in the guidance document entitled ''Providing Information About Pediatric Uses of Medical Devices—Guidance for Industry and Food and Drug Administration Staff.'' OMB previously approved the information collection related to uses outside an approved indication under OMB control number 0910–0762. As the information collection uses the same data and relies upon the same legal authority as OMB control number 0910–0748, we have discontinued OMB control number 0910–0762 and merged the information collection accordingly. Additionally, we have altered the title of the collection to reflect all collections of pediatric uses.

Our estimated burden for the information collection reflects an overall increase of 632 hours and a corresponding increase of supplements and of uses outside of approved indications. We attribute this adjustment to an increase in the number of supplements we received over the last 5 years and merging data from discontinued OMB control number 0910–0762.

Dated: November 22, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Health Center Patient Survey, OMB No. 0915–0368—Reinstatement

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments

submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30-day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than January 2, 2020.

ADDRESSES: Submit your comments, including the ICR Title, to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to 202–395–5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–1984.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Health Center Patient Survey OMB No. 0915–0368—Reinstatement.

Abstract: HRSA supported health centers (those entities funded under section 330 of the Public Health Service (PHS) Act) deliver comprehensive, affordable, quality primary health care to over 28 million patients nationwide, regardless of their ability to pay. Nearly 1,400 health centers operate approximately 12,000 service delivery sites in every U.S. state, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, and the Pacific Basin. In the past, HRSA has conducted the Health Center Patient Survey (HCPS), which surveys patients of HRSA-funded health centers. The HCPS collects information about sociodemographic characteristics, health conditions, health behaviors, access to and utilization of health care services, and satisfaction with health care received at HRSA-funded health centers. The reinstatement of the HCPS will utilize the same modules from the 2014 HCPS (OMB #0915–0368). Overarching changes will streamline the questionnaire to minimize burden, standardize questions with other national surveys to enable comparative analyses with particular focus on HHS and HRSA priority areas (*e.g.,* mental health and substance use). Survey results come from in-person, one-on-one interviews with patients who are selected as nationally representative of the Health Center Program patient population.

A 60-day notice was published in the **Federal Register** on July 24, 2019, vol. 84, No. 142; pp. 35683–84. There were two public comments.

Need and Proposed Use of the Information: The HCPS is unique because it focuses on comprehensive, nationally representative, individual level data from the perspective of health center patients. By investigating how well HRSA-funded health centers meet health care needs of the medically underserved and how patients perceive their quality of care, the HCPS serves as an empirically based resource to inform HRSA policy, funding, and planning decisions.

HRSA updated this Notice to reflect the following changes since the publication of the 60-day Notice. The number of estimated respondents changed from 9,058 to 9,000. This change came about because of the separation of the cognitive testing package from the national survey package. Based on completing the cognitive testing, the estimated overall burden on survey respondents dropped from 1.25 hours to 1.00 hour. HRSA discontinued use of the term ''Grantee'' when referring to recipients of HRSA funding; therefore, in its place in the burden table below, the term ''Grantee Recruitment'' has been changed to ''Awardee Recruitment.'' HRSA added a Short Blessed Scale to account for the patient's time if they are screened for impairment before or during the survey administration. HRSA utilized The Short Blessed Scale for 0.2 percent of respondents in the 2014 HCPS.

Likely Respondents: Patients at HRSA-supported health centers.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Awardee Recruitment	220	1	220	2.00	440.00
Site Recruitment and Training	700	1	700	3.15	2,205.00
Patient Screening	13,120	1	13,120	0.17	2,230.40
Patient Screening: Short Blessed Scale	18	1	18	0.05	0.90
Patient Survey	9,000	1	9,000	1.00	9,000.00
Total National Study	23,058	.....	23,058	.....	13,876.30

Maria G. Button,

Director, Executive Secretariat.

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