for one to five years). Cooperative agreements may have only a few funded recipients or more than 50 (such as when a CDC program provides funding to all states and territories).

To monitor the performance of recipients and CDC programs toward achieving outcomes specified by cooperative agreements, CDC currently uses the PPMR (OMB Control Number-0920–1132, Expiration Date: 08/31/2019), a progress report form adapted from an information collection owned by the Administration for Children and Families (ACF). This tool may be used to collect information periodically from recipients of CDC funds regarding the progress made on CDC funded projects.

The Performance Measures Project will work with up to 25 CDC programs developing cooperative agreements to address the challenges they face with performance planning, measurement and monitoring. Each cooperative agreement will provide funding to an average of 35 local entities, for a total of up to 875 locally funded entities.

Through participation in this Project, CDC programs and recipients of cooperative agreement funds will: (1) Develop strong performance measurement systems and practices; (2) define and operationalize priority performance measures tailored to a specific cooperative agreement; and (3) establish common data collection and reporting expectations across all recipients for a specific cooperative agreement. The Project focuses on addressing these issues during the early stages of cooperative agreement development and implementation.

The Project proposes a generic clearance adapted from a previously approved generic clearance (OMB Control Number: 0970–0490, Expiration Date 1/31/2020) owned by ACF. This ACF generic clearance replaces the information collection that is the basis of CDC's current PPMR. Project participants will customize sample information collections to meet program-specific needs. The information collected will enable the accurate, reliable, uniform and timely submission to CDC of each recipient's progress and performance measures.

The information collected by the generic information collection is designed to align with, and support the goals outlined for each of the CDC recipients. Collection and reporting of the information will occur in an efficient, standardized, and user-friendly manner that will generate a variety of routine and customizable reports. The generic information collection will allow each recipient to summarize activities and progress towards meeting performance measures and goals over a specified time period specific to each award. CDC will also have the capacity to generate reports that describe activities across multiple recipients. In addition, CDC will use the information collected to respond to inquiries from HHS, Congress and other stakeholder inquiries about program activities and their impact. CDC requests OMB approval for three years. The total estimated burden is 35,000 hours. There is no cost to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
CDC Award Recipients	(A) Performance Measures Project Sample Performance Measure Technical Specification Instrument. (B) Performance Measures project Sample Performance Measure Reporting Instrument.	875	1	40

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2019–17285 Filed 8–12–19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–1593]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Device Accessories

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 September 12, 2019.

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 0910–0823. Also include the FDA docket number found in brackets in the heading of this document.

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

Medical Device Accessories

OMB Control Number 0910–0823—Extension

FDA's guidance document ''Medical Device Accessories—Describing Accessories and Classification Pathways'' (the Accessories guidance) [1] is intended to provide guidance to industry and FDA staff about the regulation of accessories to medical devices, to describe FDA's policy concerning the classification of accessories, and to discuss the application of this policy to devices that are commonly used as accessories to other medical devices. In addition, the guidance explains what devices FDA

[1] The guidance document is available on FDA's website (*https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm429672.pdf*).

generally considers an ''accessory'' and describes the processes under section 513(f)(6) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360c(f)(6)) to allow requests for risk- and regulatory control-based classification of accessories.

We are requesting OMB approval to revise this information collection request (ICR) by adding burden estimates for two new accessory classification pathways created by the FDA Reauthorization Act of 2017 (FDARA) (Pub. L. 115–52).

FDARA changed how FDA regulates medical device accessories. Specifically, section 707 of FDARA added section 513(f)(6) to the statute and requires that FDA, upon request, classify existing and new accessories notwithstanding the classification of any other device with which such accessory is intended to be used. This means that the classification of an accessory may not be the same as its parent device, depending on the risks of the accessory when used as intended and the level of regulatory controls necessary for reasonable assurance of safety and effectiveness of the accessory. Until an accessory is distinctly classified, its existing classification will continue to apply. This provision does not preclude a manufacturer from submitting a De Novo request for an accessory.

When the Accessories guidance originally issued, FDA encouraged the use of the De Novo classification process to allow manufacturers to request risk- and regulatory control-based classification of accessories of a new type. FDA's recommendations in the guidance represented a new information collection as an accessory classification De Novo request. The information collected for an accessory classification De Novo request is substantially the same as a De Novo request (since approved under OMB control number 0910–0844), is submitted in the same manner, and has the same estimated information collection burden. The burden estimate associated with ''De Novo request under 21 U.S.C. 513(f)(2)(i)'' and ''De Novo request under 21 U.S.C. 513(f)(2)(ii),'' in OMB control number 0910–0844, includes De Novo requests for accessories. We have determined that the burden estimate for ''Accessory Classification De Novo Requests'' in this ICR (Accessory Classification Requests; OMB control number 0910–0823) is redundant and have, therefore, removed it.

Depending on an accessory's regulatory history, there are different submission types, tracking mechanisms, and deadlines:

(1) Existing accessory types are those that have been identified in a classification regulation or granted marketing authorization as part of a 510(k), pre-market application (PMA), or De Novo request (approved under OMB control numbers 0910–0120, 0910–0231, and 0910–0844, respectively). Manufacturers with marketing authorization for an existing accessory may request appropriate classification through a new stand-alone premarket submission (Existing Accessory Request). Upon request, FDA is required to meet with a manufacturer or importer to discuss the appropriate classification of an existing accessory prior to submitting a written request. Existing Accessory Requests will be initially tracked as ''Q-submissions'' (approved under OMB control number 0910–0756). FDA has a statutory deadline of 85 calendar days to respond to an Existing Accessory Request.

(2) New accessory types are those that have not been granted marketing authorization as part of a 510(k), PMA, or De Novo request. Manufacturers may include new accessories into a 510(k) or PMA with the parent device (New Accessory Request). New Accessory Requests will have the same deadline as the 510(k) or PMA. Therefore, new accessory types should follow the applicable Medical Device User Fee Amendments of 2017 deadline for the parent submission. The decision for New Accessory Requests will be separate from the decision for the marketing application.

For both Existing and New Accessory Requests, manufacturers must request proper classification of their accessory in the submission and include draft special controls, if requesting classification into class II. The processes that we use to classify an accessory will be like those used for De Novo requests. If FDA grants the Accessory Request, FDA must issue an order establishing a new classification regulation for the accessory type. If FDA denies the Accessory Request, FDA must issue a letter with a detailed description and justification for our determination.

In the **Federal Register** of April 4, 2019 (84 FR 13296), 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	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Existing Accessory Request	15	1	15	40	600
New Accessory Request	10	1	10	40	400
Total					1,000

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

We expect to receive approximately 15 Existing Accessory Requests and 10 New Accessory Requests per year. Based on estimates by FDA administrative and technical staff who are familiar with the submission process for accessory classification requests, we estimate that the ''Average Burden per Response'' for both Existing and New Accessory Requests will be approximately 40 hours per submission.

Our estimated burden for the information collection reflects an overall decrease of 440 hours and an increase of 17 responses. Factors contributing to the revision of the burden estimate include the addition of the two new accessory classification pathways created by FDARA and the removal of redundant burden described earlier in this document.

Dated: August 6, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–17346 Filed 8–12–19; 8:45 am]

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