DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; ACF Performance Progress Report, ACF–OGM–SF–PPR–B

AGENCY: Office of Grants Management, Administration for Children and Families, HHS.

ACTION: Request for public comment.

SUMMARY: The Office of Grants Management (OGM), in the Administration for Children and Families (ACF) is requesting a 3-year extension of the form ACF–OGM–SF–PPR–B (OMB #0970–0406, expiration 9/30/2019). There are no changes requested to the form.

DATES: *Comments due within 30 days of publication.* OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: *OIRA_SUBMISSION@OMB.EOP.GOV,* Attn: Desk Officer for the Administration for Children and Families.

Copies of the proposed collection may be obtained by emailing *infocollection@acf.hhs.gov.* Alternatively, copies can also be obtained by writing to the Administration for Children and Families, Office of Planning, Research, and Evaluation, 330 C Street, SW, Washington, DC 20201, Attn: OPRE Reports Clearance Officer. All requests, emailed or written, should be identified by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The ACF Office of Grants Management proposes to continue collecting program performance data for ACF's discretionary grantees using the existing ACF–OGM–SF–PPR–B (OMB #0970–0406, expiration 9/30/2019) form with no changes. The form, developed by OGM, was created from the basic template of the OMB-approved reporting format of the Program Performance Report. OGM uses this data to ensure grantees are proceeding in a satisfactory manner in meeting the approved goals and objectives of the project, and if funding should be continued for another budget period.

The requirement for grantees to report on performance is OMB grants policy. Specific citations are contained in 45 CFR part 75 Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards.

Respondents: All ACF Discretionary Grantees. State governments, Native American Tribal governments, Native American Tribal Organizations, Local Governments, and Nonprofits with or without 501(c)(3) status with the IRS.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total burden hours	Annual burden hours
ACF–OGM–SF–PPR–B	6,000	6	1	36,000	12,000

Estimated Total Annual Burden Hours: 12,000.

(Authority: 45 CFR part 75).

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2019–22343 Filed 10–11–19; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–2565]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; 510(k) Third-Party Review Program

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 November 14, 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 0910–0375. 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.

510(k) Third-Party Review Program

OMB Control Number 0910–0375—Extension With Revision

Information collections (ICs) associated with the 510(k) third-party (3P510k) review program have been approved under OMB control number 0910–0375. We request extension, including revisions, of the information collection approval as described in this document.

Section 210 of the Food and Drug Administration Modernization Act of 1997 (FDAMA) established section 523 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360m), directing FDA to accredit persons in the private sector to review certain premarket notifications (510(k)s; see 21 U.S.C. 360(k)). Participation in the 3P510k review program by accredited persons is entirely voluntary. A third party wishing to participate will submit a request for accreditation to FDA. Accredited third-party reviewers have the ability to review a manufacturer's 510(k) submission for selected devices. After reviewing a submission, the reviewer will forward a copy of the 510(k) submission, along with the

reviewer's documented review and recommendation, to FDA. Third-party reviewers should maintain records of their 510(k) reviews and a copy of the 510(k) for a reasonable period of time, usually 3 years.

Respondents to this information collection are businesses or other for-profit organizations.

In the **Federal Register** of September 14, 2018 (83 FR 46742), FDA announced the availability of the draft guidance entitled ''510(k) Third-Party Review Program; Draft Guidance for Industry, Food and Drug Administration Staff, and Third-Party Review Organizations.'' The draft guidance was intended to provide a comprehensive look into FDA's current thinking regarding the 3P510k review program authorized under the FD&C Act. Under the FDA Reauthorization Act of 2017, FDA was directed to issue draft guidance on the factors that will be used in determining whether a class I or class II device type, or subset of such device types, is eligible for review by an accredited person. The 3P510k review program is intended to allow review of devices by third-party 510k review organizations (3PROs) to provide manufacturers of these devices an alternative review process that allows FDA to best utilize our resources on higher risk devices.

The September 14, 2018, notice requested comment on the draft guidance and related revision of the information collection in OMB control number 0910–0375. We describe and respond below to the comments related to the information collection. We have numbered each comment to help distinguish between different comments. We have grouped similar comments together under the same number, and, in some cases, we have separated different issues discussed in the same comment and designated them as distinct comments for purposes of our responses. The number assigned to each comment or comment topic is purely for organizational purposes and does not signify the comment's value or importance or the order in which comments were received.

(Comment 1) One comment suggested that the 3P510k review program reduces the burden for FDA staff and industry and increases the burden on patients and doctors to figure out which devices are safe and which are not.

Another comment suggested that FDA has not demonstrated that its proposed changes to the 3P510k review program will benefit patients and that the 3P510k review program reduces patient safety, rather than protecting patients from potentially harmful devices.

(Response 1) FDA disagrees with these comments. Section 523 of the FD&C Act requires FDA to accredit persons for the purpose of reviewing reports submitted under section 510(k) of the FD&C Act and making a recommendation to FDA. All devices subject to the 510(k) requirements, including devices cleared through the 3P510k review program, must demonstrate substantial equivalence to a legally marketed device prior to introduction into interstate commerce (see 21 U.S.C. 360(k), 360(n), 360c(f)(1) and 360c(i); 21 CFR 807.92(a)(3)). Under the 3P510k review program, the objective is for the 3PRO to provide a review equivalent to that of an FDA reviewer, including making a recommendation, which it submits to FDA. FDA reviews that information to make a final determination of substantial equivalence and where appropriate, FDA will limit its review to a supervisory-level review. Therefore, the burden to demonstrate substantial equivalence remains unchanged.

In addition, this guidance describes the factors FDA will use to ensure only appropriate device types are eligible for the 3P510k review program and benefits the public health by allowing new, low-to-moderate risk devices to obtain FDA-equivalent review while enabling FDA to focus more resources on higher risk and more complex devices that necessitate more rigorous review benefitting the public health. Accordingly, no change to the guidance is necessary.

(Comment 2) One comment suggested that the proposed definition of a 510(k) Submitter is too narrow by referring to ''scientific and technical data'' and should be revised to reflect the additional components of a 510(k) submission, such as intended use.

(Response 2) FDA agrees that a 510(k) submission can include more than scientific and technical data. Rather than trying to define the appropriate components of a 510(k) submission in this guidance, FDA has modified the definition of 510(k) Submitter by removing reference to submitting ''scientific and technical data.''

(Comment 3) One comment requested clarification regarding to whom the 3PROs should provide copies of written communications between the 510(k) submitter and the 3PRO and, if these copies are submitted to FDA, that this is unnecessarily burdensome to both the 510(k) submitter and the 3PRO.

(Response 3) FDA agrees that this language should be, and therefore it has been, clarified as FDA's intent was that these communications would be provided to FDA and that the context of these communications is the communication and response to deficiencies in the submission. However, FDA disagrees that providing the Agency this information is unnecessarily burdensome. FDA believes that to understand and evaluate whether the 3PRO conducted an FDA-equivalent review, it is necessary to understand how the 3PRO documented and communicated any deficiencies it found during its review, how the 510(k) submitter responded to those deficiencies, and how the 3PRO evaluated those responses.

(Comment 4) Several comments suggested that the language in the guidance is unclear as to whether the 510(k) submitter should provide the 3PRO with all subsequent correspondence that the submitter has with FDA and that once a 3PRO has submitted its recommendation to FDA that any substantive interactions between FDA and the 510(k) submitter are not always relevant and any mandate to supply such correspondence creates additional burden.

Additionally, a comment requested clarification regarding to whom the 3PRO should provide a copy of all written communications.

(Response 4) To the extent that the commenter refers to subsequent correspondence on the 510(k) submission in question, FDA disagrees with the comment. The 3PRO's responsibilities to provide an FDA-equivalent review do not end with the initial submission to FDA. As discussed in subsection VI.J of the guidance, FDA will contact the 3PRO by telephone or email if additional information is needed. FDA not only expects the 3PRO to communicate with the 510(k) submitter to resolve any issues needing the submitter's input, FDA also expects the 3PRO to thoroughly evaluate any responses received and to document those in its updated review memo. Therefore, the 3PRO should be involved in any discussions between FDA and the 510(k) submitter regarding the request for additional information. FDA does not believe that the continued involvement of the 3PRO creates an unnecessary burden given their responsibilities, whereas their involvement in those discussions ensures the response is evaluated in a timely and efficient manner.

(Comment 5) One comment requested clarification on what a new review memo provided by a 3PRO in response to FDA's request for additional information should include or whether a documented evaluation result referring to the evaluation of the 510(k)

submitter's responses to FDA's request for additional information is sufficient.

(Response 5) FDA has clarified in the final guidance that the initial review memo provided by the 3PRO should be updated with this new information in response to FDA's request for additional information. This is consistent with FDA's expectation that the 3PRO provide a review equivalent to that of an FDA reviewer.

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

Estimated Annual Reporting Burden

Requests for accreditation (initial): On average, the Agency has received one application for accreditation for 3P510k review per year. There is no change to this information collection (IC) from the currently approved burden estimate.

Requests for accreditation (re-recognition): We have added an IC for re-recognition requests to be consistent with the guidance, which states that requests for re-recognition will be handled in the same manner as initial recognition requests. Based on the estimated number of 3PROs (seven) and the frequency of re-recognition (3 years), we expect to receive approximately two re-recognition requests per year. We expect the average burden per response to be the same as an initial request (24 hours).

510(k) reviews conducted by accredited third parties: Based on FDA's recent experience with this program, we estimate the number of 510(k)s submitted for third-party review to be 147 annually; approximately 21 annual reviews for each of the 7 3PROs. This IC has been adjusted based on current trends, however, there is no program change to this IC.

Complaints: The guidance recommends that the 3PRO should forward to FDA information on any complaint (*e.g.,* whistleblowing) it receives about a 510(k) submitter that could indicate an issue related to the safety or effectiveness of a medical device or a public health risk. Therefore, we have added an IC for complaints to the reporting burden. We expect to receive one forwarded complaint per year. Based on similar information collections, we estimate the average burden per complaint to be 0.25 hours (15 minutes).

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 [2]
Requests for accreditation (initial) [3]	1	1	1	24	24
Requests for accreditation (re-recognition) [5]	2	1	2	24	48
510(k) reviews conducted by accredited third parties [4]	7	21	147	40	5,880
Complaints [5]	1	1	1	0.25	1
Total					5,953

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Totals have been rounded.
[3] There is no change to this IC from the currently approved burden estimate.
[4] This IC has been adjusted based on current trends, however, there is no program change to this IC.
[5] This IC revises OMB control number 0910–0375 to reflect the draft guidance entitled ''510(k) Third Party Review Program; Draft Guidance for Industry, Food and Drug Administration Staff, and Third-Party Review Organizations.''

Estimated Annual Recordkeeping Burden

510(k) reviews: The 3PROs should retain copies of all 510(k) reviews and associated correspondence. Based on FDA's recent experience with this program, we estimate the number of 510(k)s submitted for 3P510k review to be 147 annually; approximately 21 annual reviews for each of the 7 3PROs. We estimate the average burden per recordkeeping to be 10 hours. The estimated number of records and recordkeepers have been adjusted based on current trends, however, there is no program change to this IC.

Records regarding qualifications to receive FDA recognition as a 3PRO: Under section 704(f) of the FD&C Act (21 U.S.C. 374(f)), a 3PRO must maintain records that support their initial and continuing qualifications to receive FDA recognition, including documentation of the training and qualifications of the 3PRO and its personnel; the procedures used by the 3P510k review organization for handling confidential information; the compensation arrangements made by the 3PRO; and the procedures used by the 3PRO to identify and avoid conflicts of interest. Additionally, the draft guidance states that 3PROs should retain information on the identity and qualifications of all personnel who contributed to the technical review of each 510(k) submission and other relevant records. Therefore, we have added an IC for ''Records regarding qualification to receive FDA recognition as a 3PRO.'' Because most of the burden of compiling the records is expressed in the reporting burden for requests for accreditation, we estimate the maintenance of such records to be 1 hour per recordkeeping annually.

Recordkeeping system regarding complaints: Section 523(b)(3)(F)(iv) of the FD&C Act requires 3PROs to agree in writing that they will promptly respond and attempt to resolve complaints regarding their activities. The guidance recommends that 3PROs establish a recordkeeping system for tracking the submission of those complaints and how those complaints were resolved, or attempted to be resolved. Therefore, we have added an IC for ''Recordkeeping system regarding complaints.'' Based on our experience with the program and the recommendations in the guidance, we estimate the average burden per recordkeeping to be 2 hours.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
510(k) reviews [2]	7	21	147	10	1,470

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]—Continued

Activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Records regarding qualifications to receive FDA recognition as a 3PRO [3]	7	1	7	1	7
Recordkeeping system regarding complaints [3]	7	1	7	2	14
Total					1,491

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] This IC has been adjusted based on current trends, however, there is no program change to this IC.
[3] This IC revises OMB control number 0910–0375 to reflect the draft guidance entitled ''510(k) Third Party Review Program; Draft Guidance for Industry, Food and Drug Administration Staff, and Third-Party Review Organizations.''

We revised our estimates for OMB control number 0910–0375 by adding new ICs, changing the title of the IC request, and adjusting the existing ICs based on current trends. Despite the addition of new ICs, the estimated burden reflects an overall decrease of 5,580 hours. We attribute this adjustment to a decrease in the number of submissions we received over the last few years.

The draft guidance also refers to previously approved ICs found in FDA regulations. The ICs in 21 CFR part 807, subpart E have been approved under OMB control number 0910–0120; the ICs regarding 3P510k review of medical devices under FDAMA have been approved under OMB control number 0910–0375; the ICs for the device appeals processes have been approved under OMB control number 0910–0738; the ICs for the Q-Submission Program (Requests for Feedback on Medical Device Submissions) have been approved under OMB control number 0910–0756.

Dated: October 4, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–22345 Filed 10–11–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–1021]

Notice to Public of Website Location of Center for Devices and Radiological Health Fiscal Year 2020 Proposed Guidance Development

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the website location where the Agency will post two lists of guidance documents that the Center for Devices and Radiological Health (CDRH or the Center) intends to publish in fiscal year (FY) 2020. In addition, FDA has established a docket where interested persons may comment on the priority of topics for guidance, provide comments and/or propose draft language for those topics, suggest topics for new or different guidance documents, comment on the applicability of guidance documents that have issued previously, and provide any other comments that could benefit the CDRH guidance program and its engagement with stakeholders. This feedback is critical to the CDRH guidance program to ensure that we meet stakeholder needs.

DATES: Submit either electronic or written comments by December 16, 2019.

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 December 16, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 16, 2019. 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–2012–N–1021 for ''Notice to Public of website Location of CDRH Fiscal Year 2020 Proposed Guidance Development.'' 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