

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.

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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, PRASStaff@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