Children and Families, U.S. Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: The Administration for Children and Families (ACF), Office of Early Childhood Development (ECD) is requesting revisions to the Tribal Maternal, Infant, and Early Childhood Home Visiting Program (Tribal MIECHV) Guidance for Submitting Reports to the Secretary (Office of Management and Budget (OMB) #0970–0409; expiration September 30, 2024). Guidance under this OMB number includes that for an annual report and that for a final report. This request is for review of the final report guidance. There are no changes proposed to the guidance for the annual report.

DATES: *Comments due within 30 days of publication.* OMB must make a decision about 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 within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. You can also obtain copies of the proposed collection of information by emailing *infocollection@acf.hhs.gov.* Identify all emailed requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: Section 511(e)(8)(A) of Title V of the Social Security Act requires that grantees under the MIECHV Program for states and jurisdictions submit an annual and a final report to the Secretary of Health and Human Services regarding the program and activities carried out under the program, including such data and information as the Secretary shall require. Section 511(h)(2)(A) further states that the requirements for the MIECHV grants to tribes, tribal organizations, and urban Indian organizations are to be consistent, to the greatest extent practicable, with the requirements for grantees under the MIECHV Program for states and jurisdictions.

ECD, in collaboration with the Health Resources and Services Administration, Maternal and Child Health Bureau awarded grants for the Tribal MIECHV Program (Tribal Home Visiting) to support cooperative agreements to conduct community needs assessments; plan for and implement high-quality, culturally relevant, evidence-based home visiting programs in at-risk tribal communities; establish, measure, and report on progress toward meeting performance measures in six legislatively mandated benchmark areas; and conduct rigorous evaluation activities to build the knowledge base on home visiting among Native populations.

After the first grant year, Tribal Home Visiting grantees must comply with the requirement to submit an annual report to the Secretary that should feature activities carried out under the program during the past reporting period, and a final report to the Secretary during the final year of their grant. To assist grantees with meeting these requirements, ACF created guidance for grantees to use when writing their reports. The annual and final report guidance specifies that grantees must address the following:

- Update and reflections on meeting Home Visiting Program Goals and Objectives
- Update and reflections on Home Visiting Programs in Targeted Community(ies)
- Update and reflections on meeting Legislatively Mandated Benchmark Requirements
- Update and reflections on Rigorous Evaluation Activities
- Update and reflections on Home Visiting Program Continuous Quality Improvement (CQI) Efforts
- Update and reflections on Dissemination Activities
- Update and reflections on Administration of Home Visiting Program
- Update and reflections on Technical Assistance Needs

Previously, the guidance included information about both the annual and the final reports from grantees. In 2021, ECD separated out the annual report guidance and received OMB approval for that in September 2021. ECD is now requesting review of guidance specific to the final report.

Respondents: Tribal Home Visiting Managers (information collection does not include direct interaction with individuals or families that receive the services).

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual number of responses per respondent	Average burden hours per response	Annual burden hours
Annual Report to the Secretary	30	1	25	750
Final Report to the Secretary	30	* .33	25	248

* Note that this is estimated to be .33 because grantees provide one final report over the three-year approval period.

Estimated Total Annual Burden Hours: 998.

Authority: Title V of the Social Security Act, sections 511(e)(8)(A) and 511(h)(2)(A).

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2022–28427 Filed 12–29–22; 8:45 am]

BILLING CODE 4184–43–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Temporary Assistance for Needy Families (TANF) Financial Report, ACF–196T (OMB #0970–0345)

AGENCY: Office of Family Assistance, Administration for Children and Families, U.S. Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: The Administration for Children and Families (ACF) is requesting a 3-year extension of the Temporary Assistance for Needy Families (TANF) Financial Report, Form ACF–196T (Office of Management and Budget (OMB) #0970–0345, expiration April 30, 2023). ACF is proposing minor

updates to the form to remove a reporting line-item reference that was associated with an expired program expenditure and minor edits to the instructions and formatting to better the presentation of the document.

DATES: *Comments due within 30 days of publication.* OMB must make a decision about 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 within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. You can also obtain copies of the proposed collection of information by emailing *infocollection@acf.hhs.gov.* Identify all emailed requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: Grantees of the TANF program are required by statute to report financial data on a quarterly basis. Form ACF–196T is used by tribal agencies administering the TANF program to report these quarterly expenditure data and to request quarterly grant funds. Failure to collect the data would seriously compromise the Office of Family Assistance and ACF's ability to monitor TANF expenditures and compliance with statutory requirements. These data are also needed to estimate outlays and to prepare reports and budget submissions for Congress.

Respondents: Tribal agencies receiving a direct grant from OFA to administer a TANF program.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual number of responses per respondent	Average burden hours per response	Annual burden hours
TANF Financial Report, Form ACF–196T	51	4	1.5	306

Estimated Total Annual Burden Hours: 306.

Authority: Social Security Act, Section 409 and 411; 45 CFR 286.245–286.285.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2022–28423 Filed 12–29–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–2375]

Authorization of Emergency Use of an In Vitro Diagnostic Device in Response to an Outbreak of Mpox; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of an Emergency Use Authorization (EUA) (the Authorization) under the Federal Food, Drug, and Cosmetic Act (FD&C Act) in response to an outbreak of mpox. FDA has issued an Authorization for an in vitro diagnostic device as requested by Roche Molecular Systems, Inc. The Authorization contains, among other things, conditions on the emergency use of the authorized product. The Authorization follows the August 9, 2022, determination by the Secretary of Health and Human Services (HHS) that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of U.S. citizens living abroad, and that involves monkeypox virus. On the basis of such determination, the Secretary of HHS declared, on September 7, 2022, that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of infection with the monkeypox virus, including in vitro diagnostics that detect and/or diagnose infection with non-variola *Orthopoxvirus,* pursuant to the FD&C Act, subject to terms of any authorization issued under that section. The Authorization, which includes an explanation of the reasons for issuance, is reprinted in this document.

DATES: The Authorization is effective as of November 15, 2022.

ADDRESSES: Submit written requests for a single copy of the EUA to the Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4338, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a Fax number to which the Authorization may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the Authorization.

FOR FURTHER INFORMATION CONTACT: Jennifer Ross, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4332, Silver Spring, MD 20993–0002, 301–796–8510 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb–3) allows FDA to strengthen public health protections against biological, chemical, nuclear, and radiological agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations. With this EUA authority, FDA can help ensure that medical countermeasures may be used in emergencies to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by biological, chemical, nuclear, or radiological agents when there are no adequate, approved, and available alternatives (among other criteria).

II. Criteria for EUA Authorization

Section 564(b)(1) of the FD&C Act provides that, before an EUA may be issued, the Secretary of HHS must declare that circumstances exist justifying the authorization based on one of the following grounds: (1) a determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a biological, chemical, radiological, or nuclear agent or agents; (2) a