60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Establishment of Exchanges and Qualified Health Plans; *Use:* As directed by the Establishment of Exchanges and Qualified Health Plans; Exchange Standards for Employers (77 FR 18310) final rule, each Exchange assumed responsibilities related to the certification and offering of QHPs. Under 45 CFR 156.280(e)(5)(ii), each QHP issuer that offers non-excepted abortion services must submit to the State Insurance Commissioner a segregation plan describing how the QHP issuer establishes and maintains separate payment accounts for any QHP covering non-excepted abortion services, and pursuant to § 156.280(e)(5)(iii), each QHP issuer must annually attest to compliance with PPACA section 1303 and applicable regulations. This segregation plan is used to verify that the QHP issuer's financial and other systems fully conform to the segregation requirements required by the PPACA.

The Centers for Medicare and Medicaid Services (CMS) is renewing this information collection request (ICR) in connection with the segregation plan requirement under 45 CFR 156.280(e)(5)(ii). The burden estimate for this ICR included in this renewal package reflects the time and effort for QHP issuers to submit a segregation plan that demonstrates how the QHP issuer segregates QHP funds in accordance with applicable provisions of generally accepted accounting requirements, circulars on funds management of the Office of Management and Budget and guidance on accounting of the Government Accountability Office. CMS is also renewing the ICR in connection with the annual attestation requirement under 45 CFR 156.280(e)(5)(iii). The burden estimate for this ICR reflects the time and effort associated with QHP issuers submitting an annual attestation to the State Insurance Commissioner attesting to compliance with section 1303 of the PPACA. *Form Number:* CMS–10400 (OMB control number: 0938–1156); *Frequency:* Annually; *Affected Public:* Private Sector (business or other for-profits, not-for-profit institutions); *Number of Respondents:* 210; *Number of Responses:* 210; *Total Annual Hours:* 580. (For questions regarding this collection contact Michele Oshman at 410–786–4396).

2. *Type of Information Collection Request:* Extension without change of a currently approved collection; *Title of Information Collection:* QHP Issuers Data Collection for Notices for Plan or Display Errors Special Enrollment Periods; *Use:* The Patient Protection and Affordable Care Act (Pub. L. 111–148) and Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), collectively referred to as the PPACA, established new competitive private health insurance markets called Marketplaces, or Exchanges, which gave millions of Americans and small businesses access to qualified health plans (QHPs), including stand-alone dental plans (SADPs)— private health and dental insurance plans that have been certified as meeting certain standards.

In the final rule, the Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2017 (CMS–9937–F), we finalized 45 CFR 156.1256, which requires QHP issuers, in the case of a material plan or benefit display error included in 45 CFR 155.420(d)(12), to notify their enrollees of the error and the enrollees' eligibility for a special enrollment period (SEP) within 30 calendar days after the issuer is informed by an Federally-facilitated Exchange (FFE) that the error is corrected, if directed to do so by the FFE. This requirement provides notification to QHP enrollees of errors that may have impacted their QHP selection and enrollment and any associated monthly or annual costs, as well as the availability of an SEP under § 155.420(d)(12) for the enrollee to select a different QHP, if desired. The Centers for Medicare and Medicaid Services (CMS) is renewing this information collection request (ICR) in connection with standards regarding Plan or Display Errors SEPs. *Form Number:* CMS–10595 (OMB control number: 0938–1301); *Frequency:* Yearly; *Affected Public:* Private Sector (business or other for-profits, not-for-profit institutions); *Number of Respondents:* 505; *Total Annual Responses:* 3,400; *Total Annual Hours:* 1,700. (For questions regarding this collection contact Deborah Hunter at 202–309–1098).

Dated: July 23, 2019.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2019–15917 Filed 7–25–19; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Native Employment Works (NEW) Program Plan Guidance and Report Requirements, (OMB No.: 970–0174)

AGENCY: Division of Tribal TANF Management, Office of Family Assistance, Administration for Children and Families; HHS.

ACTION: Request for public comment.

SUMMARY: The Administration for Children and Families (ACF) is requesting a three-year extension of the form OFA–0086, NEW Plan Guidance and NEW Program Report (OMB #0970–0174, expiration 7/31/2019). There are changes requested to these forms.

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 NEW program plan guidance documents specify the information needed to complete a NEW program plan and explains the process

for plan submission every third year and to complete the annual program report. The program plan is the application for NEW program funding and documents how the grantee will carry out its NEW program. The program report provides HHS, Congress, and grantees information to document and assess the activities and accomplishments of the NEW program. ACF proposes to extend data collection with revisions, including the deletion of guidance for NEW programs included in Public Law 102–477 programs.

Respondents: Indian tribes and tribal coalitions that run NEW programs.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Annual burden hours
NEW program plan guidance for non-477 Tribes	[1] 14	1	29	406
NEW program report	[2] 42	1	15	630

[1] We estimate that 42 of the 78 NEW grantees will not include their NEW programs in Public Law 102–477 projects. 42 grantees divided by 3 (because grantees submit the NEW plan once every 3 years) = 14.

[2] We estimate that 42 of the 78 NEW grantees will not include their NEW programs in Public Law 102–477 projects and therefore will submit the NEW program report to HHS.

Estimated Total Annual Burden Hours: 1036 [3]

Authority: 42 U.S.C. 612.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2019–15909 Filed 7–25–19; 8:45 am]

BILLING CODE 4184–36–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0007]

Generic Drug User Fee Rates for Fiscal Year 2020

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Federal Food, Drug, and Cosmetic Act (FD&C Act or statute), as amended by the Generic Drug User Fee Amendments of 2017 (GDUFA II), authorizes the Food and Drug Administration (FDA, Agency, or we) to assess and collect fees for abbreviated new drug applications (ANDAs), drug master files (DMFs), generic drug active pharmaceutical ingredient (API) facilities, finished dosage form (FDF) facilities, contract manufacturing organization (CMO) facilities, and generic drug applicant program user fees. In this document, FDA is announcing fiscal year (FY) 2020 rates for GDUFA II fees.

FOR FURTHER INFORMATION CONTACT: Melissa Hurley, Office of Financial Management, Food and Drug Administration, 4041 Powder Mill Rd., Rm. 61075, Beltsville, MD 20705–4304, 240–402–4585.

SUPPLEMENTARY INFORMATION:

I. Background

Sections 744A and 744B of the FD&C Act (21 U.S.C. 379j-41 and 379j-42) establish fees associated with human generic drug products. Fees are assessed on: (1) Certain types of applications for human generic drug products; (2) certain facilities where APIs and FDFs are produced; (3) certain DMFs associated with human generic drug products; and (4) generic drug applicants who have approved ANDAs (the program fee) (see section 744B(a)(2) to (5) of the FD&C Act).

GDUFA II stipulates that user fees should total $493,600,000 annually adjusted each year for inflation. For FY 2020, the generic drug fee rates are: ANDA ($176,237), DMF ($57,795), domestic API facility ($44,400), foreign API facility ($59,400), domestic FDF facility ($195,662), foreign FDF facility ($210,662), domestic CMO facility ($65,221), foreign CMO facility ($80,221), large size operation generic drug applicant program ($1,661,684), medium size operation generic drug applicant program ($664,674), and small business generic drug applicant program ($166,168). These fees are effective on October 1, 2019, and will remain in effect through September 30, 2020.

II. Fee Revenue Amount for FY 2020

GDUFA II directs FDA to use the yearly revenue amount determined under the statute as a starting point to set the fee rates for each fee type. For more information about GDUFA II, please refer to the FDA website (*https://www.fda.gov/gdufa*). The ANDA, DMF, API facility, FDF facility, CMO facility, and generic drug applicant program fee (GDUFA program fee) calculations for FY 2020 are described in this document.

The base revenue amount for FY 2020 is $501,721,201. This is the amount calculated for the prior fiscal year, FY 2019, pursuant to the statute (see section 744B(b)(1) of the FD&C Act). GDUFA II specifies that the $501,721,201 is to be adjusted for inflation increases for FY 2020 using two separate adjustments—one for personnel compensation and benefits (PC&B) and one for non-PC&B costs (see sections 744B(c)(1)(B) and (C) of the FD&C Act).

The component of the inflation adjustment for PC&B costs shall be one plus the average annual percent change in the cost of all PC&B paid per full-time equivalent position (FTE) at FDA for the first 3 of the 4 preceding fiscal years, multiplied by the proportion of PC&B costs to total FDA costs of human generic drug activities for the first 3 of the preceding 4 fiscal years (see section 744B(c)(1)(B) of the FD&C Act).

Table 1 summarizes the actual cost and total FTEs for the specified fiscal years, and provides the percent change from the previous fiscal year and the average percent change over the first 3 of the 4 fiscal years preceding FY 2020. The 3-year average is 3.1175 percent.

[3] Two additional programs joined the Public Law 102–477 since the publication of FR1, hence the burden is different.