move toward self-sufficiency, and improve their overall well-being. To meet these objectives, this study will include an impact and implementation study.

The impact study will involve participants being randomly assigned to either a ''program group,'' who will be paired with a coach, or to a ''control group,'' who will not be paired with a coach. The effectiveness of the coaching will be determined by differences between members of the program and control groups in outcomes such as obtaining and retaining employment, earnings, measures of self-sufficiency, and measures of self-regulation.

The implementation study will document coaching practices, describe lessons learned from implementing coaching, and enhance interpretation of the impact study findings.

The proposed information collection activities are: (1) Baseline data collection: Collection of characteristics data on all study participants as they enroll in the study. Data will be entered into the Random Assignment, Participant Tracking Enrollment, and Reporting (RAPTER) system; (2) First follow-up survey: Collection of outcome data for a subset of study participants about 9 months after random assignment; (3) Semi-structured staff interviews: Collection of qualitative data on the design and implementation of the program; (4) Staff survey: Collection of information on staff members' professional backgrounds, training, coaching practices, and attitudes; (5) In-depth participant interviews: Collection of detailed information about the participants' backgrounds and experiences with coaching; (6) Staff reports of program service receipt: Collection of data on coaching and other program services received by study participants and entered into RAPTER; and (7) Video recordings of coaching sessions: Collection of data on the interaction between the coaches and participants.

A second follow-up survey will be administered approximately 21 months after random assignment. This data collection activity will be included under a separate OMB submission.

Respondents: Program staff and individuals enrolled in the Evaluation of Employment Coaching for TANF and Other Low-Income Populations. Program staff may include coaches, case managers, workshop instructors, job developers, supervisors, and managers. All participants will be able to opt out of participating in the data collection activities.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Annual burden hours
Baseline data collection—study participants	6,000	2,000	1	0.33	660
Baseline data collection—staff	60	20	100	0.33	660
First follow-up survey	2,400	800	1	1	800
Semi-structured staff interviews	66	22	1	1.5	33
Staff survey	48	16	1	0.75	12
In-depth participant interviews	24	8	1	2.5	20
Staff reports of program service receipt	30	10	5,200	0.03	1,560
Video recordings of coaching sessions	27	9	10	0.10	9

Estimated Total Annual Burden Hours: 3,754.

Additional Information: Copies of the proposed collection may 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 should be identified by the title of the information collection. Email address: *OPREinfocollection@acf.hhs.gov.*

OMB Comment: 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. 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.

Mary Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2017–18226 Filed 8–28–17; 8:45 am]

BILLING CODE 4184–09–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Refugee Assistance Program Estimates: CMA–ORR–1.

OMB No.: 0970–0030.

Description: The ORR–1, Cash and Medical Assistance (CMA) Program Estimates, is the application for grants under the CMA program. The application is required by the Office of Refugee Resettlement (ORR) program regulations at 45 CFR 400.11(b). The regulation specifies that States must submit, as their application for this program, estimates of the projected costs they anticipate incurring in providing cash and medical assistance for eligible recipients and the costs of administering the program. Under the CMA program, States are reimbursed for the costs of providing these services and benefits for eight months after an eligible recipient arrives in this country. The eligible recipients for these services and benefits are refugees, Amerasians, Cuban and Haitian Entrants, asylees, Afghans and Iraqi with Special Immigrant Visas, and victims of a severe form of trafficking. States that provide services for unaccompanied refugee minors also provide an estimate for the cost of these services for the year for which they are applying for grants.

ORR proposes streamlining language to make the instructions easier to read. ORR proposes adding language for clarification and consistency across programs. Additionally, ORR proposes to require states to submit copies of their contracts with URM providers with the submission.

Respondents: State Agencies, the District of Columbia, Replacement

Designees under 45 CFR 400.301(c), and Wilson-Fish Grantees (State 2 Agencies) administering or supervising the administration of programs under Title IV of the Act.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ORR–1, Cash and Medical Assistance Program Estimates	55	1	0.60	33

Estimated Total Annual Burden Hours: 33.

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW., Washington, DC 20201. Attention Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *infocollection@acf.hhs.gov*.

OMB Comment: 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. 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.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2017–18254 Filed 8–28–17; 8:45 am]

BILLING CODE 4184–45–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 2018

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Generic Drug User Fee Amendments of 2017 (GDUFA II), authorizes FDA 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 the Food and Drug Administration (FDA or Agency) is announcing fiscal year (FY) 2018 rates for GDUFA fees.

FOR FURTHER INFORMATION CONTACT: David Haas, Office of Financial Management, Food and Drug Administration, 8455 Colesville Rd., COLE–14202I, Silver Spring, MD 20993–0002, 240–402–9845.

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) the generic drug applicant program (see section 744B(a)(1)–(5) of the FD&C Act).

GDUFA II fees vary greatly from those in GDUFA I because of two fundamental adjustments to the fee structure:

(1) The revenue base for GDUFA II is $493.6 million versus $323 million in the final year of GDUFA I—ANDAs are the primary workload driver of the program. GDUFA I was built on the assumption that FDA would receive 750 ANDAs per year. Over the first 4 years of GDUFA I, ANDA receipts have averaged approximately 1,000 per year. To address the increased workload, FDA hired additional staff and is projected to spend about $430 million in the final year of GDUFA I. To maintain FDA's current productivity and implement negotiated improvements, GDUFA II stipulates that user fees should total $493.6 million annually adjusted each year for inflation.

(2) GDUFA II will for the first time rely on annual program fees—GDUFA II shifts the fee burden somewhat from facility fees.

For FY 2018, the generic drug fee rates are: ANDA ($171,823), DMF ($47,829), domestic API facility ($45,367), foreign API facility ($60,367), domestic FDF facility ($211,087), foreign FDF facility ($226,087), domestic CMO facility ($70,362), foreign CMO facility ($85,362), large size operation generic drug applicant program ($1,590,792), medium size operation drug applicant program ($636,317), and small business generic drug applicant program ($159,079). These fees are effective on October 1, 2017, and will remain in effect through September 30, 2018.

II. Fee Revenue Amount for FY 2018

The base revenue amount for FY 2018 is $493,600,000, as set in the statute (see section 744B(b)(1) of the FD&C Act). GDUFA II directs FDA to use the yearly revenue amount as a starting point to set the fee rates for each fee type. For more information about GDUFA II, please refer to the FDA Web site (*http://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 2018 are described in this document.

GDUFA II specifies that the $493,600,000 is to be adjusted for inflation increases for FY 2019 through FY 2022 using two separate adjustments—one for personnel compensation and benefits (PC&B) and one for non-PC&B costs (see section 744B(c)(1) of the FD&C Act). Because the adjustment for inflation does not take effect until FY 2019, FDA will not adjust the base revenue amount for inflation in FY 2018.

III. ANDA Fee

Under GDUFA II, the FY 2018 ANDA fee is owed by each applicant that submits an ANDA on or after October 1, 2017. This fee is due on the receipt date of the ANDA. Section 744B(b)(2)(B) specifies that the ANDA fee will make up 33 percent of the $493,600,000, which is $162,888,000.

To calculate the ANDA fee, FDA estimated the number of full application equivalents (FAEs) that will be submitted in FY 2018. An ANDA counts as one FAE; however, 75 percent of the