recommendations to the Secretary of HHS and the Administrator of CMS regarding the following questions as it relates to these codes:

- Should the code be included on the CLFS?
- If the code should be included on the CLFS, what method of payment should be used to price the test codes (crosswalking or gapfilling, as required by 42 CFR 414.507(g))?
- If crosswalking, specify the crosswalk code(s).

The Panel will also provide input on other CY 2018 CLFS issues that are designated in the Panel's charter and specified on the meeting agenda.

II. Agenda

The Agenda for the September 25, 2017, Panel Meeting will provide for discussion and comment on the following topics as designated in the Panel's charter:

- CY 2018 CLFS laboratory test codes for which CMS received no applicable information to calculate a Medicare payment rate and was posted on August 4, 2017, on the CMS Web site at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Laboratory_Public_Meetings.html.*
- Other CY 2018 CLFS issues designated in the Panel's charter and further described on our Agenda.
- CDLTs that will be discussed during this meeting is available on the CMS Web site, in the document entitled ''2017 Clinical Laboratory Test Codes with No Data,'' at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Laboratory_Public_Meetings.html.*

A detailed Agenda will be posted approximately 1 week before the meeting, on the CMS Web site at *https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonClinicalDiagnosticLaboratoryTests.html.*

III. Special Accommodations

Individuals requiring special accommodations must include the request for these services during registration.

IV. Meeting Participation

This meeting is open to the public. As noted previously, the public may participate in the meeting via teleconference, webcast, and webinar. There will not be an in-person meeting location for this public Panel meeting. In addition, meeting registration is required to access the meeting.

V. Panel Recommendations and Discussions

The Panel's recommendations will be posted after the meeting on the CMS Web site at *https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonClinicalDiagnosticLaboratoryTests.html.*

VI. Additional Information

A. Webinar, Webcast, and Teleconference Meeting Information

The Panel meeting will be conducted only via webinar, webcast or by teleconference. The meeting registration information, teleconference dial-in instructions, and related webcast and webinar details will be posted on the meeting agenda, which will be available on the CMS Web site approximately 1 week prior to the meeting at *https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonClinicalDiagnosticLaboratoryTests.html.*

B. Meeting Registration

Registration is required to participate in this teleconference public meeting. Interested participants will be able to access the registration, teleconference, webcast, and webinar instructions, by following the instructions on the meeting agenda. There is no deadline for meeting registration.

C. Deadline for Submission of Presentations

There will be an opportunity during the meeting for public presentations and oral comments. During the meeting, an individual will be limited to 1 minute of comments for each laboratory test code. All presenters for the meeting must register and submit their presentations and comments electronically to our CLFS dedicated email mailbox, *CDLTPanel@cms.hhs.gov,* by the date listed in the **DATES** section of this notice. Presenters should submit all presentations and comments using a standard PowerPoint template that is available on the CMS Web site at *https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonClinicalDiagnosticLaboratoryTests.html,* under the ''Panel Meetings'' heading.

VI. Copies of the Charter

The Secretary's Charter for the Advisory Panel on Clinical Diagnostic Laboratory Tests is available on the CMS Web site at *http://cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonClinicalDiagnosticLaboratoryTests.html* or you may obtain a copy of the charter by submitting a request to the contact listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice.

VII. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Dated: September 8, 2017.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2017–19539 Filed 9–11–17; 4:15 pm]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Refugee Data Submission System for Formula Funds Allocation—ORR–5.

OMB No.: 0970–0043.

Description: The information collection, Refugee Data Submission System for Formula Funds Allocations, (ORR–5) satisfies the statutory requirements of the Immigration and Nationality Act (INA). Section 412(a)(3) of the Act requires the Director of the Office of Refugee Resettlement (ORR) to make a periodic assessment, based on refugee population and other relevant factors, of the relative needs of refugees for assistance and services and the resources available to meet those needs. This includes compiling and maintaining data on the secondary migration of refugees within the United States after arrival. Further, INA 412(c)(1)(B) states that formula funds shall be allocated based on the total number of refugees, taking into account secondary migration.

Respondents: States or replacement designees.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ORR–5 Form	50	1	22	1,100

Estimated Total Annual Burden Hours: 1,100.

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. 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. 2017–19467 Filed 9–13–17; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–0007]

Biosimilar User Fee Rates for Fiscal Year 2018

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the rates for biosimilar user fees for fiscal year (FY) 2018. The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Biosimilar User Fee Amendments of 2017 (BsUFA II), authorizes FDA to assess and collect user fees for certain activities in connection with biosimilar biological product development; review of certain applications for approval of biosimilar biological products; and each biosimilar biological product approved in a biosimilar biological product application.

BsUFA II directs FDA to establish, before the beginning of each fiscal year, the amount of initial and annual biosimilar biological product development (BPD) fees, the reactivation fee, and the biosimilar biological product application and program fees for such year. These fees apply to the period from October 1, 2017, through September 30, 2018.

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 744G, 744H, and 744I of the FD&C Act (21 U.S.C. 379j–51, 379j–52, and 379j–53), as amended by BsUFA II (title IV of the FDA Reauthorization Act of 2017, Pub. L. 115–52), authorizes the program of fees for biosimilar biological products. Under section 744H(a)(1)(A) of the FD&C Act, the initial BPD fee for a product is due when the sponsor submits an investigational new drug (IND) application that FDA determines is intended to support a biosimilar biological product application or within 5 calendar days after FDA grants the first BPD meeting, whichever occurs first. A sponsor who has paid the initial BPD fee is considered to be participating in FDA's BPD program for that product.

Under section 744H(a)(1)(B) of the FD&C Act, once a sponsor has paid the initial BPD fee for a product, the annual BPD fee is assessed beginning with the next fiscal year. The annual BPD fee is assessed for the product each fiscal year until the sponsor submits a marketing application for the product that is accepted for filing, or discontinues participation in FDA's BPD program.

Under section 744H(a)(1)(D) of the FD&C Act, if a sponsor has discontinued participation in FDA's BPD program and wants to re-engage with FDA on development of the product, the sponsor must pay a reactivation fee to resume participation in the program. The sponsor must pay the reactivation fee by the earlier of the following dates: No later than 5 calendar days after FDA grants the sponsor's request for a BPD meeting for that product, or upon the date of submission by the sponsor of an IND describing an investigation that FDA determines is intended to support a biosimilar biological product application. The sponsor will be assessed an annual BPD fee beginning with the first fiscal year after payment of the reactivation fee.

BsUFA II also authorizes fees for certain biosimilar biological product applications and for each biosimilar biological product identified in an approved biosimilar biological product application (sections 744H(a)(2) and 744H(a)(3) of the FD&C Act). Under certain conditions, FDA may grant a small business a waiver from its first biosimilar biological product application fee (section 744H(d)(1) of the FD&C Act).

For FY 2018, the fee revenue amount is $45,000,000, adjusted as needed to reflect an updated assessment of the workload for the process for the review of biosimilar biological product applications. FDA is adjusting the FY 2018 revenue amount to $40,214,000 (rounded to the nearest thousand dollars) reflecting its updated assessment of the likely workload for the BsUFA program in FY 2018.

This document provides fee rates for FY 2018 for the initial and annual BPD fee ($227,213), for the reactivation fee ($454,426), for an application requiring clinical data ($1,746,745), for an application not requiring clinical data ($873,373), and for the program fee ($304,162). These fees apply to the period from October 1, 2017, through September 30, 2018. For applications that are submitted for this period, this FY 2018 fee schedule must be used.

II. Fee Revenue Amount for FY 2018

The fee revenue amount for FY 2018 is $45,000,000 adjusted for updated workload estimates (see sections 744H(b)(1) and 744H(c)(4) of the FD&C Act).

A. Statutory Fee Revenue Adjustments for Inflation

BsUFA II specifies that the annual fee revenue amount is to be further adjusted for inflation increases for FY 2019 through FY 2022 using two separate adjustments—one for personnel