also manages all data collected on youth served in the URM program.

C. The Unaccompanied Alien Children's Programs is directly responsible in providing care and services to unaccompanied alien children who are referred to ORR for care pending immigration status, or identified as victims of trafficking. The Unaccompanied Alien Children's Program consists of the Division of Unaccompanied Alien Children's Operations, the Division of Planning and Logistics, and the Division of Unaccompanied Alien Children's Health. The Program maintains statistical information and data on each child and any actions concerning the child while the child is under the Director's care. The Unaccompanied Alien Children's Programs includes compliance teams who conducts oversight of allegations of abuse, monitoring and inspections of facilities, and placement locations in which unaccompanied alien children reside. Unaccompanied Alien Children Program staff ensures that services are administered in a manner that supports child welfare standards of care and services and complete regular monitoring of service provision. The Deputy Director reports directly to the Director of ORR.

The Director of the Division of Unaccompanied Alien Children's Operations implements intake and placement decisions for all unaccompanied alien children. The Division supports specialized care through grants and contracts. The Division ensures consideration of the child's best interest in care and custody decisions. The Division coordinates all decisions related to sponsor reunification, background checks, home assessments, follow-up services, medical assessment and treatment, and repatriation. The Division administers the pro bono legal services and child advocate programs, and compiles a state-by-state list of professionals or entities qualified to provide the children with a guardian and attorney representational services. The Division also supports grants for services provided to children after their release from ORR care.

The Director leads the Division of Planning and Logistics and oversees the development of a comprehensive strategic plan to ensure that the Unaccompanied Alien Children Programs is able to anticipate and meet capacity needs. The Planning and Logistic Division will lead a continuous improvement plan. The Division prepares plans for temporary increases in shelter capacity and staffing, as well as temporary changes in ORR staffing to support continued Unaccompanied Children Program operations. The Division leads coordination with other federal agencies and work with other Unaccompanied Alien Children's divisions to support influx response. If ORR experiences an influx in referrals of unaccompanied children, the team leads influx response operations and logistics.

The Director of the Division of Unaccompanied Alien Children's Health oversees the provision of health and medical services to unaccompanied children in ORR care. The Division reviews and approves orders for complex medical procedures and reviews test results for certain medical ailments. The Division also ensures reporting of public health information to the appropriate public health authorities.

III. Continuation of Policy. Except as inconsistent with this reorganization, all statements of policy and interpretations with respect to organizational components affected by this notice within ACF, heretofore issued and in effect on this date of this reorganization are continued in full force and effect.

IV. Delegation of Authority. All delegations and re-delegations of authority made to officials and employees of affected organizational components will continue in them or their successors pending further re-delegations, provided they are consistent with this reorganization.

V. Funds, Personnel, and Equipment. Transfer of organizations and functions affected by this reorganization shall be accompanied in each instance by direct and support funds, positions, personnel, records, equipment, supplies, and other resources.

This reorganization will be effective upon date of signature.

Delegation of Authority. Directives or orders by the Assistant Secretary of the Administration of Children and Families, all delegations and redelegations of authority made to officials and employees of affected organizational components will continue in them or their successors pending further redelegations, provided they are consistent with this reorganization.

(Authority: 44 U.S.C. 3101.)

Dated: December 1, 2020.

Megan E. Steel,

Office of the Executive Secretariat, Administration for Children and Families.

[FR Doc. 2020–28706 Filed 12–28–20; 8:45 am]

BILLING CODE 4184–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2012–N–0197; FDA–2017–N–1095; FDA–2011–N–0424; FDA–2017–N–2021 and FDA–2010–N–0493]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the internet at *https://www.reginfo.gov/public/do/PRAMain*. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB control No.	Date approval expires
Shortages Data Collection	0910–0491	05/31/2021
Electronic Submission of Allegations of Regulatory Misconduct Associated with Medical Devices	0910–0769	11/30/2023

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB—Continued

Title of collection	OMB control No.	Date approval expires
Temporary Marketing Permit Applications	0910–0133	12/31/2023
Channels of Trade Policy for Commodities with Residues of Pesticide Chemicals for Which Tolerances Have Been Revoked, Suspended, or Modified by the EPA	0910–0562	12/31/2023
Additional Criteria and Procedures for Classifying Over-the-Counter Drugs as Generally Recognized as Safe and Effective and Not Misbranded	0910–0688	12/31/2023

Dated: December 21, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–28608 Filed 12–28–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–2246]

Fee Rates Under the Over-the-Counter Monograph Drug User Fee Program for Fiscal Year 2021

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the fee rates under the Over-the-Counter (OTC) Monograph Drug user fee program for fiscal year (FY) 2021. On March 27, 2020, a new section was added to the Federal Food, Drug, and Cosmetic Act (FD&C Act) by the Coronavirus Aid, Relief, and Economic Security Act, which authorizes FDA to assess and collect user fees from qualifying manufacturers of OTC monograph drugs and submitters of OTC monograph order requests. FDA refers to the OTC Monograph Drug user fee program as ''OMUFA'' throughout this document. This notice establishes the OMUFA fee rates for FY 2021.

FOR FURTHER INFORMATION CONTACT: David Haas, 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

Section 744M of the FD&C Act (21 U.S.C. 379j–72) authorizes FDA to assess and collect: (1) Facility fees from qualifying owners of OTC monograph drug facilities and (2) fees from submitters of qualifying OTC monograph order requests. These fees are to support FDA's OTC monograph drug activities, which are detailed in section 744L(6) of the FD&C Act (21 U.S.C. 379j–71(6)) and include various FDA activities associated with OTC monograph drugs and inspection of facilities associated with such products. For OMUFA purposes:

- An OTC monograph drug is a nonprescription drug without an approved new drug application which is governed by the provisions of section 505G of the FD&C Act ((21 U.S.C. 355h); see section 744L(5) of the FD&C Act);
- An OTC monograph drug facility is a foreign or domestic business or other entity that, in addition to meeting other criteria, is engaged in manufacturing or processing the finished dosage form of an OTC monograph drug (see section 744L(10) of the FD&C Act). The Agency refers to such facility as Monograph Drug Facility (MDF);
- A contract manufacturing organization (CMO) facility is an OTC monograph drug facility where neither the owner nor any affiliate of the owner or facility sells the OTC monograph drug produced at such facility directly to wholesalers, retailers, or consumers in the United States (see section 744L(2) of the FD&C Act); and
- An OTC monograph order request (OMOR) is a request for an administrative order, with respect to an OTC monograph drug, which is submitted under section 505G(b)(5) of the FD&C Act (see section 744L(7) of the FD&C Act).

FDA will assess and collect facility fees with respect to the two types of OTC monograph drug facilities—MDF and CMO facilities. A full facility fee will be assessed to each qualifying person that owns a facility identified as an MDF (see section 744M(a)(1)(A) of the FD&C Act), and a reduced facility fee of two-thirds will be assessed to each qualifying person that owns a facility identified as a CMO facility (see section 744M(a)(1)(B)(ii) of the FD&C Act). The facility fees are due 45 days after the date of publication [1] of this notice (see section 744M(a)(1)(D)(i) of the FD&C Act). As discussed below, OTC monograph drug facilities are exempt from FY 2021 facility fees if they had ceased OTC monograph drug activities, and updated their registration with FDA to that effect, prior to December 31, 2019 (see section 744M(a)(1)(B)(i) of the FD&C Act).

In addition to facility fees, the Agency will assess and collect fees from submitters of OMORs, except for OMORs which request certain safety-related changes (as discussed below). There are two levels of OMOR fees, based on whether the OMOR at issue is a Tier 1 or Tier 2 OMOR.[2]

For FY 2021, the OMUFA fee rates are as follows: Tier 1 OMOR fees ($500,000), Tier 2 OMOR fees ($100,000), MDF facility fees ($14,060), and CMO facility fees ($9,373). These fees are effective as of October 1, 2020, and will remain in effect through September 30, 2021. This document describes the calculations used to set the OMUFA facility fees and OMOR fees for FY 2021.

II. Facility Fee Revenue Amount for FY 2021

A. Base Fee Revenue Amount

Under OMUFA, FDA sets annual facility fees to generate the total facility fee revenues for each fiscal year established by section 744M(b) of the FD&C Act. The yearly base revenue amount is the starting point for setting annual facility fee rates. The base revenue amount for FY 2021 is $8,000,000 (see section 744M(b)(3)(A) of the FD&C Act).

B. Fee Revenue Adjustment for Inflation

Under OMUFA, the annual base revenue amount for facility fees is adjusted for inflation for FY 2022 and each subsequent FY (see section

[1] Although under section 744M(c)(4)(A) of the FD&C Act, FDA was to publish this notice not later than the second Monday in May of 2020, we note that under section 744M(f)(1) of the FD&C Act, OMUFA fees ''shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts''. An appropriation of FY 2021 OMUFA fees was provided under section 123 of the Continuing Appropriations Act, 2021, Division A of Public Law 116–159 (October 1, 2020).

[2] Under OMUFA, a Tier 1 OMOR is defined as any OMOR which is not a Tier 2 OMOR (see section 744L(8) of the FD&C Act). Tier 2 OMORs are detailed in section 744L(9) of the FD&C Act.