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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

[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 Pub. L. 116-159 (October 1, 2020).

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 744M(c)(1) of the FD&C Act). Because the adjustment for inflation does not apply until FY 2022, the FY 2021 facility fee revenue is not subject to an inflation adjustment by FDA.

C. Fee Revenue Adjustment for Additional Direct Cost

[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.

Under OMUFA, $14,000,000 is added to the facility fee revenues for FY 2021 to account for additional direct costs (see section 744M(c)(3)(A) of the FD&C Act).

D. Fee Revenue Adjustment for Operating Reserve

Under OMUFA, FDA may further increase the FY 2021 facility fee revenue and fees if such an adjustment is necessary in order to provide up to 3 weeks of operating reserves of carryover user fees for OTC monograph drug activities (see section 744M(c)(2)(A) of the FD&C Act). However, under the statute, if the carryover balance exceeds 10 weeks of operating reserves, FDA is required to decrease fees to provide for not more than 10 weeks of operating reserves of carryover user fees (see section 744M(c)(2)(C) of the FD&C Act).

FDA is applying the operating reserve adjustment to increase the FY 2021 facility fee revenue and fees to enable the Agency to maintain 3 weeks of operating reserves of carryover user fees. To determine the 3-week operating reserve amount, the FY 2021 annual base revenue adjusted for additional direct costs (i.e., $8,000,000 + $14,000,000 = $22,000,000), is divided by 52, and then multiplied by 3. The 3-week operating reserve amount for FY 2021 is $1,269,231.

As a result of the above calculations, the final FY 2021 OMUFA target facility fee revenue is $23,269,000 (rounded to the nearest thousand dollars).

III. Determination of FY 2021 OMOR Fees

Under OMUFA, the FY 2021 Tier 1 OMOR fee is $500,000 and the Tier 2 OMOR fee is $100,000 (see section 744M(a)(2)(A)(i) and (ii) of the FD&C Act, respectively). OMOR fees are not included in the OMUFA target revenue calculation, which is based on the facility fees (see section 744M(b)(1) of the FD&C Act).

An OMOR fee is generally assessed to each person who submits an OMOR (see section 744M(a)(2)(A) of the FD&C Act). OMOR fees are due on the date of the submission of the OMOR (see section 744M(a)(2)(B) of the FD&C Act). The payor should submit the OMOR fee that applies to the type of OMOR they are submitting (i.e., Tier 1 or Tier 2). FDA will determine

whether the requestor has submitted the appropriate OMOR fee following receipt of the OMOR and the fee.

An OMOR fee will not be assessed if the OMOR seeks to make certain safety changes with respect to an OTC monograph drug. Specifically, no fee will be assessed if FDA finds that the OMOR seeks to change the drug facts labeling of an OTC monograph drug in a way that would add to or strengthen: (1) a contraindication, warning, or precaution; (2) a statement about risk associated with misuse or abuse; or (3) an instruction about dosage and administration that is intended to increase the safe use of the OTC monograph drug (see section 744M(a)(2)(C) of the FD&C Act).

IV. Facility Fee Calculations

A. Facility Fee Revenues and Fees

For FY 2021, facility fee rates are being established to generate a total target revenue amount equal to $23,269,000 (rounded to the nearest thousand dollars). FDA used the methodology described below to determine the appropriate number of MDF and CMO facilities to be used in setting the OMUFA facility fees for FY 2021. FDA took into consideration that the CMO facility fee is equal to two-thirds of the amount of the MDF facility fee (see section 744M(a)(1)(B)(ii) of the FD&C Act).

B. Estimate of the Number of Qualifying Facilities and Setting the Facility Fees

For FY 2021, FDA utilized the Agency's Electronic Drug Registration and Listing System (eDRLS) to estimate the number of qualifying MDF or CMO facilities that engage in the manufacturing or processing of the finished dosage form of an OTC monograph drug. In setting the FY 2021 facility fees, FDA considers the fee-qualifying population of OTC monograph drug facilities to be the population of establishments coded in eDRLS with the business operation qualifier of "manufactures human over-the-counter drug products produced under a monograph" or "contract manufacturing for human over-the-counter drug products produced under a monograph" and indicating at least one of the following business operations: finished dosage

form manufacture, label, manufacture, pack, relabel, or repack. FDA estimated this population through December 30, 2020, based on information provided by facilities in eDRLS during the first three calendar quarters of 2020.

Those facilities that only manufacture the active pharmaceutical ingredient (or API) of an OTC monograph drug do not meet the definition of an OTC monograph drug facility (see section 744L(10)(A)(i)(II)) of the FD&C Act). Likewise, a facility is not considered an OTC monograph drug facility if its only manufacturing or processing activities are one or more of the following: (a) production of clinical research supplies; (b) testing; or (c) placement of outer packaging on packages containing multiple products, for such purposes as creating multipacks, when each monograph drug product contained within the overpackaging is already in a final packaged form prior to placement in the outer overpackaging (see section 744L(10)(A)(iii) of the FD&C Act). In addition, as noted above, certain OTC monograph drug facilities are exempt from facility fees. Under the statute, a facility fee will not be assessed if the identified OTC monograph drug facility: (1) has ceased all activities related to OTC monograph drugs prior to December 31 of the year immediately preceding the applicable fiscal year; and (2) has updated its eDRLS registration to reflect that change (see section 744M(a)(1)(B)(i) of the FD&C Act). As the applicable fiscal year for fee-setting under this notice is FY 2021, the year immediately preceding the applicable fiscal year is FY 2020. December of FY 2020 is December 2019. Thus, a FY 2021 facility fee will not be assessed with respect to an OTC monograph drug facility that, prior to December 31, 2019, had ceased all activities related to OTC monograph drugs and updated its eDRLS registration to that effect.

FDA considered a number of factors that could affect collection of the target revenue, including that FY 2021 is the first year of this new user fee program and uncertainties related to the effects of the COVID-19 public health emergency. In estimating the total number of fee-paying facilities, the Agency made certain assumptions, including that:

(1) Facilities using expired Structured Product Labeling (SPL) codes in eDRLS were no longer manufacturing and marketing OTC monograph drugs;

(2) Facilities that have deregistered in eDRLS have exited the market;

(3) Facilities that FDA believes registered incorrectly as OTC monograph drug facilities (for example, because the associated drug listings for these facilities do not include OTC monograph drugs but instead indicate such products as OTC drug products under an approved drug application or OTC animal drug products) are not engaged in manufacturing or processing the finished dosage form of an OTC monograph drug; and

(4) Facilities that registered but do not have an active OTC monograph drug product listing associated in their registration profile are not manufacturing or processing such drug products.

Each establishment paying the facility fee is counted as one fee-paying unit. The total estimate of fee-paying units is further analyzed to determine the number of respective MDF and CMO fee-paying units.

Based on the data obtained from eDRLS, FDA estimates there will be 1,712 fee-paying units. The Agency estimates that 90 percent (1,712 x .90 = 1,541, rounded) will incur the MDF fee and 10 percent (1,712 x .10 = 171, rounded) will incur the CMO fee.

To determine the number of full fee-paying equivalents (the denominator) to be used in setting the OMUFA fees, FDA assigns a value of 1 to each MDF (1,541) and a value of 2/3 to each CMO (171 x 2/3 = 114) for a full facility equivalent of 1,655 (rounded). The target fee revenue of $23,269,000 is then divided by 1,655 for an MDF fee of $14,060 and a CMO fee of $9,373.

V. Fee Schedule for FY 2021

The fee rates for FY 2021 are displayed in table 1.

Table 1. Fee Schedule for FY 2021

Fee Category	FY 2021 Fee Rates
OMOR	
Tier 1	$500,000

Tier 2	$100,000
Facility Fees	
MDF	$14,060
CMO	$9,373

VI. Fee Payment Options and Procedures

The new fee rates are effective October 1, 2020, through September 30, 2021. To pay the OMOR, MDF, and CMO fees, complete an OTC Monograph User Fee Cover Sheet, available at: https://userfees.fda.gov/OA_HTML/omufaCAcdLogin.jsp. A user fee identification (ID) number will be generated. Payment must be made in U.S. currency by electronic check or wire transfer, payable to the order of the Food and Drug Administration. The preferred payment method is online using electronic check (Automated Clearing House (ACH) also known as eCheck) or credit card for payments under $25,000 (Discover, VISA, MasterCard, American Express).

FDA has partnered with the U.S. Department of the Treasury to use *Pay.gov*, a web-based payment application, for online electronic payment. The *Pay.gov* feature is available on the FDA website after completing the OTC Monograph User Fee Cover Sheet and generating the user fee ID number. Secure electronic payments can be submitted using the User Fees Payment Portal at https://userfees.fda.gov/pay (Note: only full payments are accepted. No partial payments can be made online). Once an invoice is located, "Pay Now" should be selected to be redirected to *Pay.gov*. Electronic payment options are based on the balance due. Payment by credit card is available for balances that are less than $25,000. If the balance exceeds this amount, only the ACH option is available. Payments must be made using U.S. bank accounts as well as U.S. credit cards.

For payments made by wire transfer, include the unique user fee ID number to ensure that the payment is applied to the correct fee(s). Without the unique user fee ID number, the payment may not be applied, which could result in FDA not filing an application and other penalties. The originating financial institution may charge a wire transfer fee. Applicable wire transfer fees

must be included with payment to ensure fees are fully paid. Questions about wire transfer fees should be addressed to the financial institution. The account information for wire transfers is as follows: U.S. Department of the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Acct. No.: 75060099, Routing No.: 021030004, SWIFT: FRNYUS33. If needed, FDA's tax identification number is 53-0196965.

Dated: December 22, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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