wiley

ALERT

OTC Drug User Facility Fees – Don't Miss the Changes!

December 30, 2020

Originally published on December 30, 2020, this article was last updated on January 6, 2021.

On January 4, 2021, FDA unexpectedly withdrew the notice entitled *Fee Rates Under the Over the Counter Monograph User Fee Program for Fiscal Year 2021* stating that it had been ordered to cease further collection efforts pending approval from the Secretary of the Department of Health and Human Services (HHS). The withdrawal notice states that the original notice issued without such Secretarial approval. Under the CARES Act, the Secretary is required to establish and collect OTC drug manufacturer facility fees annually, and further, FDA can only accept and review an OTC Monograph Order Request (OMOR) upon receipt of full payment of the OMOR fee. The HHS is significantly behind in setting, assessing, and collecting the 2021 facility fees in light of October 1, 2021 congressional appropriations to support this mandate. *See* section 123 of the Continuing Appropriations Act, 2021, Division A of Public Law 116-159. Yesterday evening, HHS tweeted a new notice that its states will be published shortly expressing its view that companies entering the market during COVID-19 to market hand sanitizer only are not subject to facility fees under the CARES Act while the pandemic is ongoing and for the year immediately following termination of the COVID-19 public health emergency. To date, a new OMUFA rate schedule has not been issued. Wiley will continue to monitor this matter.

On December 29, 2020, the U.S Food and Drug Administration (FDA) issued a notice announcing the first ever fee rates under the over-the-counter (OTC) monograph drug user fee program (OMUFA). As the reader will recall, under the Coronavirus Aid, Relief, and Economic

Authors

Ann M. Begley
Partner
202.719.4585
abegley@wiley.law

Practice Areas

Food & Drug

Security Act (CARES Act), passed on March 27, 2020, Congress significantly changed the way OTC monograph drugs are and will be regulated going forward.[1] Instead of OTC monograph drug regulations, there will be OTC monograph drug orders, and requests for changes in such orders or the addition of new orders will be the subject of OTC monograph order requests (OMORs). To fund this program and other FDA OTC drug activities, Congress legislated that manufacturers of OTC monograph drugs, and most OMOR applicants, will be subject to the new user fee program.[2]

In the OMUFA notice, FDA will assess two types of annual facility fees for OTC drug manufacturers: (1) Monograph Drug Facility (MDF) and (2) Contract Manufacturing Organization (CMO). For new order requests, the Agency will assess two levels of OMOR fees, (1) Tier 1 OMOR or (2) Tier 2 OMOR. The fees are effective October 1, 2020 through September 2021. **Facility Fees for FY 2021 are due by February 12, 2021.**

Facility Fees:

Facilities that manufacture or process finished dosage forms of an OTC monograph drug are subject to annual facility fees. Such facilities include those identified in FDA's electronic Drug Registration and Listing System (eDRLS) as manufacturers or contract manufacturers of human OTC drug products produced under a monograph that conduct at least one of the following business operations: finished dosage form manufacture, label, manufacture, pack, relabel, or repack. *OTC monograph drugs* are defined as those nonprescription drugs that are not the subject of an approved drug application, and which are governed under the newly added section 505G of the Federal Food, Drug, and Cosmetic Act (FFDCA). The two types of facilities are defined as follows:

> MDF facility: a foreign or domestic business or other entity that is engaged in manufacturing or processing the *finished* dosage form of an OTC monograph drug.
>
> CMO facility: an MDF where neither the owner or 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.

There are some exclusions from the OMUFA OTC drug monograph facility fees. The following OTC drug manufacturers need not pay the annual fee:

1. Facilities that ceased manufacturing activities prior to December 31 of the last applicable fiscal year and updated their filings in the eDRLS to reflect that change (for FY 2021, the facility must have ceased manufacturing prior to December 31, 2019 to meet this exemption),
2. Manufacturers of OTC monograph drug active pharmaceutical ingredients,
3. Manufacturers of OTC monograph drugs intended for use in the production of clinical research supplies or testing,
4. Manufacturers of OTC drugs that are subject to an approved drug application,
5. Manufacturers of homeopathic OTC drugs, and

6. Packagers of OTC monograph drugs in which the only activity is to place outer packaging on packages that contain multiple products when each OTC monograph drug product within the over packing is already in a final packaged form prior to the overpackaging operation.

Annual fees are based on the annual OMUFA target facility fee revenue which follows the fee setting calculation mandated under the CARES Act. For FY 2021, the target facility fee revenue is $23,269,000.00. Based upon a review of FDA's electronic Drug Registration and Listing System (eDRLS), FDA anticipates payments from 1541 MDFs and 171 CMOs.

For FY 2021, the facility fees are as follows: **Facility Type FY 2021 Facility Fee** MDF

$14,060.00 CMO

$9,373.00

A facility that fails to pay the OMUFA facility fee within 20 days of the due date is subject to the following penalties, which shall apply until the fee is paid:[3]

- Placement on a publicly available arrears list
- All drugs manufactured in the facility will be deemed misbranded

OMOR Fees:

The CARES Act identifies specific OTC monograph innovations that qualify as Tier 2 OMORs, and states that all other innovations fall within Tier 1. The tier level determines the OMOR fee. The following change requests qualify as Tier 2 OMORs:[4]

- reordering of existing information in the drug facts label of an OTC monograph drug,
- the addition of information to the other information section of the drug facts label of an OTC monograph drug, as limited by 21 CFR 201.66(c)(7) (or any successor regulations),
- certain modification to the directions for use section of the drug facts label of an OTC monograph drug,
- the standardization of the concentration or dose of a specific finalized ingredient within a particular finalized monograph,
- a change to ingredient nomenclature to align with nomenclature of a standards-setting organization,
- addition of an interchangeable term in accordance with 21 CFR 330.1 (or any successor regulations), or
- Any other change specified by the FDA pursuant to an order.

Everything else qualifies as a Tier 1 OMOR, which includes changes such as new OTC monograph drug ingredients, new indications, and new ingredient combinations.[5]

No fee will apply to an OMOR regardless of tier for the following safety related OTC drug monograph changes to add or strengthen:

- a contraindication, warning, or precaution
- a statement about risk associated with use or misuse
- an instruction about dosage and administration that is intended to increase the safe use of the OTC monograph drug

The OMOR fees are set by statute allowing for an annual inflation adjustment. For 2021, the OMOR fees are as follows: **OMOR Tier Level FY 2021 OMOR Fee** Tier 1

$500,000 Tier 2

$100,000

The fee must be paid at the time of the OMOR submission, and FDA will notify the submitter if the appropriate fee has been submitted, and as appropriate a refund will issue, or the additional fee must be paid.[6] A submission will be considered incomplete and not accepted for filing until the OMOR fee is fully paid.[7]

Payment Information

Both facility and OMOR fees must be paid by electronic check or wire transfer. Payment is a two-step process, first requiring the party to complete an OMUFA cover sheet in order to receive a "user fee identification number." The payor will then pay the required fee by electronic check from a U.S. Bank Account or with a U.S. credit card through the FDA electronic platform here, or by wiring FDA the funds, along with any additional wiring transfer fees, to the following address:

U.S. Department of the Treasury, TREAS NYC
33 Liberty St., New York, NY 10045
Acct. No.: 75060099, Routing No.: 021030004
SWIFT: FRNYUS33

The payor should assure that the User Fee ID is associated with payment to allow proper recording of payment by FDA.

For many manufacturers and future OMOR submitters, this may be your first experience with FDA user fees. If you have any questions about OMUFA fees or other requirements under the new OTC drug monograph provisions, we are here to assist.

---

[1] Coronavirus Aid, Relief, and Economic Security Act, Public Law 116-136, sections 3851-3862.

[2] While the CARES Act mandated publication of such fees by May 2020, the Act also required that an appropriations Act first set forth the extent and amount of such fees. In October 1, 2020, the Continuing Appropriations Act, 2021 provided for OMUFA fees.

[3] Section 744M(e)(1) of the FFDCA.

[4] Section 744L(9) of the FFDCA.

[5] As a reminder, under the new CARES Act provisions, the new 18-month exclusivity provisions are available only for Tier 1 changes resulting in effective orders that either involve a new active ingredient or another change that requires clinical data to support the change. However, exclusivity is not available for changes that concern a safety or effectiveness testing methodology or a safety-related change.

[6] Section 744M(a)(2) of the FFDCA.

[7] Section 744M(e)(2) of the FFDCA.