OTC Monograph Drug User Fee Program (OMUFA): Understanding FY 2024 User Fees and Registration

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Agenda

- What is OMUFA?
- Registration and Listing
- OMUFA User Fee Types and FY 2024 Key Dates
- COVID-19 Hand Sanitizer Manufacturers
- OMUFA FY 2024 Target Revenue and Fee Rates
- Fee Payment Process
- Penalties for Failure to Pay Fees
- Refund Eligibility

Poll Question

What is your knowledge and experience regarding the OMUFA User Fee Program?

A. I consider myself an expert on OMUFA user fees; I understand the OMUFA fee structure and the fee-paying process

B. I have limited knowledge of OMUFA user fees, and I am aware that there may be fees associated with OTC monograph drug activities

C. I have no knowledge of OMUFA user fees, and I am not aware of any fees associated with OTC monograph drug activities

What is OMUFA?

- The Coronavirus Aid, Relief, and Economic Security Act (CARES Act) was enacted on **March 27, 2020**.
- The CARES Act included an important legislative initiative that reforms and modernizes the way OTC monograph drugs are regulated in the United States.
- The CARES Act added sections 744L and 744M of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) authorizing a new user fee program dedicated to Over-the-Counter (OTC) monograph drug activities.
  - We refer to this OTC user fee program as the Over-the-Counter Monograph Drug User Fee program (or OMUFA)

What is the OMUFA User Fee Program?

- OMUFA is a congressionally-authorized program of Industry-paid fees to help fund FDA's regulatory activities for OTC monograph drugs.
- Congress's authorization of the OMUFA Program was informed by an FDA-industry agreement, embodied in a "Commitment Letter", under which FDA agreed to adhere to performance goals, including to review submissions within specific time frames.
- OMUFA fees will support FDA's OTC monograph drug activities, which are detailed in section 744L(6) of the FD&C Act and include various FDA activities associated with OTC monograph drugs and inspection of facilities associated with such products.

Common OMUFA Terms

- **OTC Monograph Drugs**
  - 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) (section 744L(5) of the FD&C Act).
- **OTC Monograph Drug Facility**
  - An OTC monograph drug facility (also referred to as MDF) 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 (section 744L(10) of the FD&C Act).
- **OTC Contract Manufacturing Organization**
  - A contract manufacturing organization (also referred to as 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 (section 744L(2) of the FD&C Act).
    - CMOs pay two-thirds of the amount of the fee paid by an MDF

Registration and Listing

- All facilities are requested to review and update their current registration information, if applicable, to accurately describe the facility's operations.
- Registering the facility using the appropriate Structured Product Labeling (SPL) Business Operation(s) and Business Operation Qualifier(s) will help FDA determine whether the facility is subject to applicable OMUFA facility fees.
- Entities may refer to the electronic Drug Registration and Listing System (eDRLS) SPL webpage at FDA SPL Business Operation Qualifiers for relevant SPL codes.

Registration and Listing

- FDA has updated SPL Business Operation Qualifiers for facilities that manufacture OTC monograph drug products including:
  - C131708 (Manufactures human over-the-counter drug products produced under a monograph)
  - C131709 (Manufactures human over-the-counter drug products produced under an approved drug application)
  - C131710 (Manufactures human over-the-counter drug products not produced under an approved drug application or under a monograph)
  - C170729 (Contract Manufacturing for human over-the-counter drug products produced under a monograph)
    - Includes those facilities with the business operations of Analysis, Pack, Label, Repack, and Relabel.

OMUFA User Fees

- The FD&C Act authorizes FDA to collect OMUFA user fees for FY 2021 through FY 2025.

- There are **two OMUFA** User Fee types:
  - Facility Fee
  - OTC Monograph Order Request (OMOR) Fee

OMUFA Facility Fee

- Assessed and due annually for qualifying facilities that engage in the manufacturing or processing of the finished dosage form of an OTC monograph drug.

- Facility user fee rates vary dependent upon the registration of the facility within FDA's eDRLS (i.e., MDF or CMO).

OMUFA Facility Fee Assessment

- Any person that owns a facility identified as an OTC monograph facility, including contract manufacturing organization facilities, on **December 31** of the fiscal year or **at any time during the preceding 12-month** period is required to pay a facility fee for that fiscal year.
- For FY 2024, if a facility was identified as an OTC monograph facility in eDRLS at any time from January 1, 2023, through December 31, 2023, the facility will be assessed an FY 2024 fee.
- There is no statutory authority under the FD&C Act for any waiver or reduction of OMUFA facility fees based on size or revenue.

COVID-19 Hand Sanitizer Manufacturers

- **Does the FY 2024 OMUFA facility fee apply to facilities that manufacture or process hand sanitizer products during the COVID-19 public health emergency?**
  - No, consistent with the Department of Health and Human Services' (HHS) Notice published on January 12, 2021, facilities that first registered with FDA on or after the January 27, 2020, declaration of the COVID-19 public health emergency (PHE) solely for purposes of manufacturing OTC hand sanitizer products during the PHE were not liable for the FY 2024 OMUFA facility fee.
  - However, since the PHE expired on May 11, 2023, those facilities that "continue to manufacture" hand sanitizer products as of December 31, 2024, will be identified as OTC monograph drug facilities and be subject to an OMUFA facility fee for FY 2025.
  - Alternatively, if such facilities cease manufacturing hand sanitizer products and delist and deregister to reflect that before 12 a.m. EST on December 31, 2024, they will not be identified as an OTC monograph drug facility and will not be considered fee liable for purposes of FY 2025 OMUFA facility fee.

Facilities That Are Not OMUFA Fee Liable

- Facilities that:
  - Manufacture human OTC drug products produced under an **approved drug** application;
  - Manufacture human OTC drug products that are **neither** produced under an approved drug application **nor** are they produced under a monograph; or
  - Have ceased all activities related to OTC monograph drugs prior to December 31 of the year immediately preceding the applicable fiscal year; and have updated their eDRLS registration to reflect that change.
    - For FY 2024, this date was December 31, 2022.
  - Only manufacture active pharmaceutical ingredient (API) for further use in the manufacturing or processing of the finished dosage form of an OTC monograph drug product.
  - For FY 2024, first registered with FDA on or after the January 27, 2020, declaration of the COVID-19 public health emergency (PHE) solely for purposes of manufacturing OTC hand sanitizer products during the PHE.

Facilities That Are Not OMUFA Fee Liable

- Facilities that engage in the following activities are not subject to the Facility Fee:
  - Manufacture or process the finished dosage form only for the production of **clinical research supplies or testing**;
  - Facilities whose only manufacturing or processing activities are the 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**

What is an OMOR?

- Per section 744L(7) of the FD&C Act, the term ‘‘OTC monograph order request’’ (or 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.
  - The function of an OMOR request is to add, remove, or change a generally recognized as safe and effective (GRASE) condition for an OTC drug monograph.
- Types of OMORs:
  - Tier 1 OMOR
  - Tier 2 OMOR

OMOR Tiers

Tier 1 OMOR	Tier 2 OMOR
• Any OMOR not determined to be a Tier 2 OMOR. Examples include **additions** of: ▪ A new ingredient to a monograph that already has one or more ingredients that have been found to be GRASE. ▪ A new indication to a monograph that already has one or more ingredients that have been found to be GRASE, and the new indication applies to one or more of the GRASE ingredients. ▪ New monograph therapeutic category (each ingredient proposed for the new therapeutic category will be a separate OMOR).	• Tier 2 OMORs may be involved in the: ▪ Reordering of existing information in the drug facts label (DFL). ▪ Addition of information to the "Other Information" section of the DFL (subject to certain limitations). ▪ Modification to the "Directions for Use" section of the DFL, consistent with a minor dosage form change. ▪ Standardization of the concentration or dose of a specific finalized ingredient within a particular finalized monograph. ▪ Change to the ingredient nomenclature to align with the nomenclature of a standards-setting organization. ▪ The addition of an interchangeable term.

OMOR Fees

- OMOR fees are:
  - Due on the date of the submission of the OMOR (except for OMORs that request certain safety-related changes).
  - Not included in the OMUFA target revenue calculation, which is based on the facility fees.
  - Assessed an OMOR fee dependent on the OMOR tier (i.e., Tier 1 or Tier 2)

Exceptions to the OMOR 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**:
    - A contraindication, warning, or precaution;
    - A statement about risk associated with misuse or abuse; or
    - 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).

FY 2024 OMUFA Fees

- The FY 2024 OMUFA target revenue for facility fees is $32,253,000 (rounded to the nearest thousand).
- The OMUFA facility fee was due on **June 3, 2024**.
  - The FY 2024 OMUFA Facility Fee FRN was published on March 29, 2024.
- The OMUFA OMOR fees are due on the date of the submission of the OMOR.
  - The FY 2024 OMUFA OMOR Fee FRN was published on September 12, 2023.

Fee Schedule for FY 2024

Facility Fee Rates	**MDF**	$34,166
	CMO	$22,777*

OMOR Fee Rates	**Tier 1**	$537,471
	Tier 2	$107,494

* A CMO pays two-thirds (2/3) of the amount of the fee paid by an MDF.

Fee Payment Process

- Industry accesses the User Fee System (an application within FDA's User Fee System) to fill out an OMUFA User Fee Cover Sheet to initiate the payment process
  - Provide specific information for each fee type (e.g., FEI of the facility on the cover sheet)
  - Submit a copy of a signed cover sheet to FDA
  - Pay the appropriate fees after completion of the cover sheet

- Payment must be made in U.S. currency from a U.S. bank by:
  - Pay.gov
    - Automated Clearing House (ACH) electronic check (eCheck)
    - Credit card payment (limit of $24,999.99)
  - Wire Transfer

Penalties for Failure to Pay Fees

OMOR Fee

- If a person owing fees fails to remit the appropriate payment when submitting an OMOR, that OMOR shall be considered incomplete and shall not be accepted for filing.

Facility Fee

- If a facility does not pay the annual facility fee within 20 calendar days of the due date (i.e., for FY 2024, this date is June 23, 2024):
  - The Agency will place the facility on a publicly-available arrears list.
  - All OTC monograph drug products produced at that facility (or containing an ingredient manufactured at that facility) shall be deemed misbranded.

Further, OMORs will not be accepted from persons owing fees in arrears (from failure to pay the OMOR or facility fee), and OTC monograph drug meeting requests from persons owing fees will be denied or cancelled.

Who Is Entitled To A Refund?

- Any OMOR that is refused for filing or withdrawn before being accepted or refused for filing shall be refunded 75 percent of the OMOR fee to the payer.
- The difference in the OMOR fee shall be refunded if FDA recharacterizes the OMOR from a Tier 1 request to a Tier 2 request.
- These situations do not require a written refund request to be submitted to the Agency.

Overpayments or Payments In Error

- Refunds for overpayments or payments made in error must be requested in writing within **180 calendar days** of payment.
- A written request **and** a completed Form FDA 3913 should be submitted to the Division of User Fee Management at CDERCollections@fda.hhs.gov.
- If you are assessed an FY 2024 OMUFA facility fee and believe your facility is not an OTC monograph drug facility as described in FDA's March 29, 2024, FRN, please contact CDERCollections@fda.hhs.gov.

Key Points

- OMUFA Statutory Background
- Updated Registration and Listing
- Annual Facility Fees
- OMOR Fees
- Fee Payment Process
- Penalties For Failure to Pay Fees

Resources

- OMUFA Cover Sheet and Payment Information
  https://userfees.fda.gov/OA_HTML/omufaCAcdLogin.jsp
- OMUFA User Fee Webpage
  www.fda.gov/OMUFA
- Questions about refunds, appeals, reconsiderations, or arrears list:
  CDERCollections@fda.hhs.gov
- OTC Monograph Reform in the CARES Act
  https://www.fda.gov/drugs/over-counter-otc-nonprescription-drugs/over-counter-otc-drug-review-otc-monograph-reform-cares-act
- OMUFA draft guidance for industry titled “Assessing User Fees Under the Over-the-Counter Monograph Drug User Fee Program”

  https://www.fda.gov/regulatory-information/search-fda-guidance-documents/assessing-user-fees-under-over-counter-monograph-drug-user-fee-program

Challenge Question #1

The FY 2024 facility fee liable period is:

A. From October 1, 2023, through September 30, 2024

B. From June 1, 2023, through June 3, 2024

C. From January 1, 2024, through December 31, 2024

D. From January 1, 2023, through December 31, 2023

Challenge Question #2

The OMUFA Facility Fee types include (Select all applicable):

A. Application Fee

B. Monograph Drug Facility (MDF) Fee

C. Program Fee

D. Contract Manufacturing Organization (CMO) Fee

E. All the above

F. B and D

G. A, B, C and D

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Questions?


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