OTC Monograph Drug User Fee Program (OMUFA): Understanding FY 2021 User Fees

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Agenda

- What is OMUFA?
- Registration and Listing
- OMUFA User Fee Types and FY 2021 Key Dates
- OMUFA FY 2021 Target Revenue and Fee Rates
- Penalties for Failure to Pay Fees
- Fee Payment Process
- Refund Eligibility
- Helpful Resources

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 modeled after the successful Prescription Drug User Fee Act (PDUFA).
- 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.

OTC Monograph Drugs

Per section 744L(5) of the FD&C Act, 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).

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) – with the caveats described on the next slide.

OTC Monograph Drug Facility

The FD&C Act's OMUFA provisions detail the definition of OTC monograph drug facilities and the requirements for FDA Establishment Identifiers (FEI) (a facility's FEI is also needed during submission of the cover sheet within FDA's User Fee System).

Section 744L(10)(A) of the FD&C Act

- Generally, an OTC monograph drug facility means a foreign or domestic business that is:
  - Under one management;
  - At one geographic location or address engaged in manufacturing or processing the finished dosage form of an OTC monograph drug;
  - Includes a finished dosage form manufacturer facility in a contractual relationship with the sponsor of one or more OTC monograph drugs to manufacture or process such drugs; and
  - Does not include a business or other entity whose only manufacturing or processing activities are the production of clinical research supplies, testing, or placement of outer packaging over drug products in final packaged form, such as for creating multipacks.

Section 744L(10)(B) of the FD&C Act

- Separate buildings or locations within close proximity are considered to be at one geographic location or address if the activities conducted in such buildings or locations are
  - closely related to the same business enterprise;
  - under the supervision of the same local management; and
  - under a single FDA establishment identifier and capable of being inspected by the Food and Drug Administration during a single inspection.

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 registration within **electronic Drug Registration and Listing System** (eDRLS) using **current Structured Product Labeling (SPL)** to accurately describe the facility's operations.
- Registering the facility using the appropriate SPL codes will help FDA determine whether the facility is subject to applicable OMUFA facility fees.
- Entities may refer to the eDRLS SPL webpage at FDA SPL Business Operation Qualifiers for relevant SPL codes.

Registration and Listing

- In March 2017, FDA updated SPL Business Operation Qualifiers for facilities that manufacture OTC monograph drug products. The updated codes are:
  - 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)
- In March 2020, FDA added an SPL Business Operation Qualifier for facilities that qualify as OTC monograph Contract Manufacturing Organizations:
  - C170729 (Contract Manufacturing for human over-the-counter drug products produced under a monograph)
    - On May 4, 2021, this eDRLS functionality was made available to 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 2021, if a facility is identified as an OTC monograph facility in eDRLS at any time from January 1, 2020, through December 31, 2020, the facility will be assessed an FY 2021 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 2021, this date was December 31, 2019.
  - 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.

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**

COVID-19 Hand Sanitizer Manufacturers

- As stated in the Department of Health and Human Services January 12, 2021, FRN, "persons that entered into the over-the-counter drug industry for the first time in order to supply hand sanitizers during the COVID-19 Public Health Emergency are not persons subject to the facility fee the Secretary is authorized to collect" under section 744M of the FD&C Act (with a caveat described on the next slide).
- As stated in FDA's March 26, 2021, FRN:
  - The term "hand sanitizer" commonly refers to consumer antiseptic rubs. However, because the HHS notice referred to "persons that entered the over-the-counter drug market to supply hand sanitizer products in response to the COVID-19 Public Health Emergency" (86 FR 2420), we are using the same terminology--"hand sanitizer products"--to refer to OTC monograph drug products intended for use (without water) as antiseptic hand rubs or antiseptic hand wipes by consumers or health care personnel, including products manufactured or prepared consistent with the Agency's "Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19) Guidance for Industry" (see https://www.fda.gov/media/136289/download).
  - Our use of the term "hand sanitizer products" in this notice to refer to antiseptic hand rubs and antiseptic hand wipes intended for use by consumers or health care personnel does not alter any existing regulatory distinctions between these products.

COVID-19 Hand Sanitizer Manufacturers

- FDA will not assess OMUFA facility fees upon those firms 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 hand sanitizer products during the PHE.
  - If a company was manufacturing hand sanitizer prior to the January 27, 2020, declaration of the COVID-19 PHE, the FY 2021 facility fees would apply and be assessed.
  - If a company were to manufacture hand sanitizer in addition to other OTC monograph drugs, the FY 2021 facility fees would apply and be assessed.
- Hand sanitizer manufacturers not subject to the OMUFA facility fees are still subject to other applicable FDA requirements.
- FDA will continue to use its regulatory compliance and enforcement tools to protect consumers, including from potentially dangerous or subpotent hand sanitizers.

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.
- Two tiers of OMOR fees:
  - Tier 1 OMOR Fee
  - Tier 2 OMOR Fee

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 2021 OMUFA Fees

- The FY 2021 OMUFA target revenue for facility fees is $23,269,000 (rounded to the nearest thousand).
- The OMUFA facility fee is due 45 calendar days after publication of FY 2021 OMUFA FRN.
  - The FY 2021 OMUFA FRN was published on March 26, 2021.
  - The FY 2021 OMUFA facility fee was due on May 10, 2021.

Fee Schedule for FY 2021

Facility Fee Rates	**MDF**	$20,322
	CMO	$13,548*

OMOR Fee Rates	**Tier 1**	$500,000
	Tier 2	$100,000

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

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:
  - 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.

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 for OMORs
  - 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

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 2021 OMUFA facility fee and believe your facility is not an OTC monograph drug facility as described in FDA's March 26, 2021, FRN, please contact CDERCollections@fda.hhs.gov.

Key Points

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

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

Challenge Question #1

The amount of a CMO facility fee is…

A. One-half of the amount of fee paid by an OTC MDF

B. There is no difference in fees between OTC CMOs and OTC MDFs

C. One-third of the amount of fee paid by an OTC MDF

D. Two-thirds of the amount of fee paid by an OTC MDF

Challenge Question #2

How can I pay my OMUFA Facility Fee?

A. Automated Clearing House electronic Check (eCheck)

B. Credit Card

C. Carrier pigeon

D. Wire Transfer

E. Written (mail-in) check

F. A, B, and D

G. A, B, D, and E

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Questions?


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