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

CAPT Matt Brancazio
Pharm.D., MBA, RAC
Branch Chief, Policy and Operations

Division of User Fee Management
Office of Management
Center for Drug Evaluation and Research, FDA

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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 performance goals, including goals 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 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 as MDF (i.e., MDF or CMO).

OMUFA Facility Fee Assessment

- Any person that owns a facility identified as an OTC monograph drug 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.
    - There is no statutory authority under the FD&C Act for any waiver or reduction of OMUFA facility fees based on business size or business revenue.
- For FY 2021, if a facility was identified as an OTC monograph drug facility in eDRLS at any time from January 1, 2020, through December 31, 2020, the facility was assessed an FY 2021 fee.

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.
  - 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

- As explained in FDA's March 26, 2021, FRN, 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, FY 2021 facility fees would apply and were assessed.
  - If a company were to manufacture hand sanitizer in addition to other OTC monograph drugs, FY 2021 facility fees would apply and were 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.

FY 2021 OMUFA Facility Fee Rates

MDF	$20,322
CMO	$13,548*

* 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

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