Assessing User Fees Under the Over-the-Counter Monograph Drug User Fee Program

Guidance for Industry

DRAFT GUIDANCE

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research

October 2022
User Fees

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Contains Nonbinding Recommendations

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Assessing User Fees Under the Over-the-Counter Monograph Drug User Fee Program Guidance for Industry[1]

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. INTRODUCTION

This guidance provides stakeholders with information regarding FDA's implementation of the Over-the-Counter Monograph Drug User Fee Program under sections 744L and 744M of the Federal Food, Drug, and Cosmetic Act (the FD&C Act),[2] as added by the Coronavirus Aid, Relief, and Economic Security Act (or the CARES Act), which authorize FDA to assess and collect user fees from qualifying manufacturers of over-the-counter (OTC) monograph drugs[3] and requestors[4] of OTC Monograph Order Requests (OMORs)[5], other than OMORs for certain safety changes. FDA refers to the OTC Monograph Drug user fee program as "OMUFA" throughout this document.

This guidance describes the types of OMUFA fees, the due dates for fee payment, and the exceptions to certain fees. In addition, this guidance describes the process for submitting fee payments to FDA, the consequences for failing to pay the required fees, and the process for submitting refund requests or disputing FDA's assessment of OMUFA fees. This guidance does not address how FDA calculates OMUFA fee rates for each fiscal year (FY), nor does it address FDA's implementation of other user fee programs administered by the Agency.[6] Throughout this guidance, references to *user fees* or *user fee program* are to over-the-counter monograph drug user fees authorized, assessed, and collected under sections 744L and 744M of the FD&C Act.

[1] This guidance has been prepared by the Division of User Fee Management, Office of Management, in the Center for Drug Evaluation and Research at the FDA.
[2] 21 U.S.C. 379j-71 and 21 U.S.C. 379j-72.
[3] See section 744L(5) of the FD&C Act which defines an OTC monograph drug as 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).
[4] Requestor is defined in section 505G(q)(3) of the FD&C Act as any person or group of persons marketing, manufacturing, processing, or developing a drug.
[5] Section 744L(7) of the FD&C Act defines an OTC monograph order request as a request submitted under section 505G(b)(5) of the FD&C Act.
[6] For example, under the Prescription Drug User Fee Act (PDUFA), Biosimilar User Fee Act (BSUFA), or Generic Drug User Fee Amendments (GDUFA).

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. BACKGROUND

The CARES Act was signed into law on March 27, 2020. Division A of the CARES Act includes an important legislative initiative, detailed in subtitle F of title III,[7] that reforms and modernizes the way OTC monograph drugs are regulated in the United States.

Accompanying this OTC monograph reform legislation, the CARES Act also added[8] FD&C Act provisions under which FDA is authorized to assess and collect user fees dedicated to OTC monograph drug activities[9] for each of FYs 2021 through FY 2025. These fees are: (1) annual facility fees from qualifying manufacturers of OTC monograph drugs; and (2) fees from requestors of OMORs, except for OMORs that request certain safety-related changes.[10] OMUFA fees provide additional resources[11] to help the Agency conduct important regulatory activities in a timely manner, as with other user fee programs administered by the Agency, and ultimately help provide the public with access to innovative OTC monograph drugs.

Development of recommendations to Congress for the reauthorization of OMUFA are expected to begin before FY 2025, the final fiscal year of OMUFA's current authorization.

III. DEFINITIONS

For purposes of this guidance:

- The term ***affiliate*** means a business entity that has a relationship with a second business entity if, directly or indirectly, (1) one business entity controls, or has the power to control, the other business entity; or (2) a third party controls, or has the power to control, both of the business entities.[12]

- The term ***contract manufacturing organization facility*** (CMO) means an OTC monograph drug facility where neither the owner of such manufacturing facility nor any affiliate of such owner or facility sells the OTC monograph drug produced at such facility directly to wholesalers, retailers, or consumers in the United States.[13]

[7] Part I of Subtitle F of title III, Division A of the CARES Act.
[8] Part II of Subtitle F of title III, Division A of the CARES Act.
[9] Section 744L(6) of the FD&C Act.
[10] Section 744M(a)(2)(C) of the FD&C Act.
[11] User fees are available for obligation in accordance with appropriations Acts.
[12] Section 744L(1) of the FD&C Act.
[13] Section 744L(2) of the FD&C Act.

- The term ***FDA establishment identifier*** (FEI) is the unique number automatically generated by FDA's Field Accomplishments and Compliance Tracking System (FACTS) (or any successor system).[14]

- The term ***OTC monograph drug*** is a nonprescription, over-the-counter (or OTC) drug that may be marketed without an approved new drug application under section 505 of the FD&C Act if it meets the requirements of section 505G of the FD&C Act, as well as other applicable requirements.[15]

- The term ***OTC monograph drug facility*** means a foreign or domestic business or other entity that:[16]
    - is under one management, either direct or indirect; and
    - is at one geographic location or address engaged in manufacturing or processing the finished dosage form[17] 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 one or more of the following: production of clinical research supplies; testing; or 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.[18]

  For purposes of this definition:

    - 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 FEI and capable of being inspected by the FDA during a single inspection.[19]

  If a business or other entity would be considered an OTC monograph drug facility, but for being under multiple management, the business or other entity is deemed to constitute multiple OTC monograph drug facilities, one per management entity.[20]

[14] Section 744L(4) of the FD&C Act.
[15] Section 744L(5) of the FD&C Act.
[16] Section 744L(10)(A).
[17] See discussion of finished dosage form in section IV, below.
[18] See discussion of overpackaging in section IV, subsection C, below.
[19] Section 744L(10)(B) of the FD&C Act,
[20] Section 744L(10)(C) of the FD&C Act.

- The term ***OTC monograph drug meeting*** means any meeting regarding the content of a proposed OTC monograph order request (OMOR).[21]

- The term ***OTC monograph order request (OMOR)*** refers to a request for an order submitted under section 505G(b)(5) of the FD&C Act.[22]

- The term ***person*** includes an affiliate of a person.[23]

- The term ***requestor*** is any person or group of persons marketing, manufacturing, processing, or developing a drug.[24]

- The term ***sponsor*** is any person marketing, manufacturing, or processing a drug that is listed under section 510(j) and is or will be subject to an administrative order of the FDA under section 505G of the FD&C Act.[25]

- The term ***Tier 1 OTC monograph order request*** means any OTC monograph order request not determined to be a Tier 2 OTC monograph order request.[26]

- The term ***Tier 2 OTC monograph order request*** means an OTC monograph order request for:
    - the 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 section 201.66(c)(7) of title 21, Code of Federal Regulations (or any successor regulations);
    - modification to the Directions for Use section of the Drug Facts label of an OTC monograph drug, if such changes conform to changes made pursuant to section 505G(c)(3)(A) of the FD&C Act;
    - 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; or
    - addition of an interchangeable term in accordance with section 330.1 of title 21, Code of Federal Regulations (or any successor regulations).[27,28]

[21] Section 744L(11) of the FD&C Act.
[22] Section 744L(7) of the FD&C Act.
[23] Section 744L(12) of the FD&C Act; see also section 201(e) of the FD&C Act.
[24] Section 505G(q)(3) of the FD&C Act.
[25] Section 505G(q)(2) of the FD&C Act.
[26] Section 744L(8) of the FD&C Act.
[27] Section 744L(9)(A) of the FD&C Act.
[28] FDA may, based on program implementation experience or other factors found appropriate by the Agency, characterize any OMOR as a Tier 2 OMOR (including recharacterizing an OMOR from Tier 1 to Tier 2) and publish such determination in a proposed order issued pursuant to section 505G of the FD&C Act. See section 744L(9)(B) of the FD&C Act.

IV. FACILITY FEES

FDA is authorized to assess and collect annual facility fees from qualifying manufacturers of OTC monograph drugs.[29] A full facility fee will be assessed to each qualifying person that owns a facility that is identified as an OTC monograph drug facility and does not meet the definition of a Contract Manufacturing Organization (CMO) facility. OTC monograph drug facilities that are assessed the full facility fee are referred to by FDA as Monograph Drug Facilities (MDF). The amount of the facility fee for a CMO is two-thirds of the full facility fee.[30]

For the first program year (FY 2021), facility fees were due 45 calendar days after publication of the FY 2021 fee rate notice in the *Federal Register*.[31, 32] For each fiscal year after FY 2021, the facility fees are due on the later of: 1) the first business day of June of such year; or 2) the first business day after the enactment of an appropriations Act providing for the collection and obligation of fees.[33]

Under OMUFA, a facility (*see* section III) that is identified as an OTC monograph drug facility (i.e., MDF or CMO) on December 31 of the fiscal year or at any time during the preceding 12-month period (e.g., for FY 2021, January 1, 2020, through December 31, 2020) is required to pay a facility fee for that fiscal year.[34]

As noted above in section III, an OTC monograph drug facility is a foreign or domestic business entity that (in addition to meeting other criteria) is engaged in manufacturing or processing the finished dosage form of an OTC monograph drug, i.e., the dosage form that the product will be in when marketed to the consumer.[35] For example:

- A facility engaged in the manufacture or processing of bulk finished tablets or capsules, for subsequent packaging and labeling by that facility (or another facility) as a marketed OTC monograph drug product, would generally be considered to be engaged in the manufacturing or processing of a finished dosage form of an OTC monograph drug.

- If the dosage form of an OTC monograph drug to be marketed to the consumer is an active pharmaceutical ingredient (API) *without* any inactive ingredients, such as in the case of products consisting solely of glycerin, mineral oil, petroleum jelly, or saline eye wash, a facility engaged in the manufacture or processing of such products would generally be considered to be engaged in the manufacturing or processing of a finished dosage form of an OTC monograph drug.

[29] Section 744M(a)(1) of the FD&C Act.
[30] Section 744M(a)(1)(B)(ii) of the FD&C Act.
[31] 86 FR 16223 (March 26, 2021).
[32] Section 744M(a)(1)(D)(i)(II) of the FD&C Act.
[33] Section 744M(a)(1)(D)(ii) of the FD&C Act.
[34] Section 744M(a)(1)(A) of the FD&C Act.
[35] See e.g., the description of finished dosage form in 21 CFR 210.3(b)(4), relating to Current Good Manufacturing Practice (CGMP) requirements: "a finished dosage form, for example, tablet, capsule, solution, etc., that contains an active ingredient, generally but not necessarily, in association with inactive ingredients".

- If a facility only manufactures an API that is intended to be included in subsequent manufacturing or processing (i.e., combining the API with inactive ingredients) of the dosage form produced by another registered facility and marketed to the consumer, then the facility manufacturing only the API would generally not be considered to be engaged in the manufacturing or processing of a finished dosage form of an OTC monograph drug.

Additionally, a facility that engages in the final steps of packaging or labeling of the finished dosage form (FDF) of the OTC monograph drug, such as placing the FDF drug products into a bottle or container or affixing the labels on the containers or packages containing the FDF, is also considered an OTC monograph drug facility subject to the OMUFA facility fee.[36]

Section 510 of the FD&C Act requires firms that manufacture, prepare, propagate, compound, or process drugs in the United States or drugs that are imported or offered for import into the United States to register with the FDA.[37] Facilities are required to review and update registration within the electronic Drug Registration and Listing System (eDRLS)[38] and should use current Structured Product Labeling (SPL) Business Operation Qualifier codes each year. Registering the facility using the appropriate SPL Business Operation Qualifier codes helps FDA in determining whether the facility is subject to an applicable OMUFA facility fee.

Entities may refer to the eDRLS SPL webpage at FDA SPL Business Operation Qualifiers[39] for the entirety of the SPL codes for further clarification and definition.

A. Facility Fee for an MDF

Under section 744M(a)(1) of the FD&C Act, "Each person that owns a facility identified as an OTC monograph drug facility on December 31 of the fiscal year or at any time during the preceding 12-month period shall be assessed an annual fee for each such facility." For example, for purposes of FY 2022 facility fees, that time period is January 1, 2021, through December 31, 2021. A full facility fee will be assessed to each person that owns a facility during the applicable time period that is identified as an OTC monograph drug facility and does not meet the definition of a CMO (see section 744M(a)(1) of the FD&C Act). A separate full facility fee will generally be assessed for each such facility owned by that person.[40]

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[36] *See* section 744L(10)(A); see also section 744L(10)(A)(iii) of the FD&C Act, excluding from the definition of "OTC monograph drug facility" those facilities whose manufacturing or processing consists solely of a narrow range of specified activities (e.g., placement of outer overpackaging on products already in final packaged form); *cf* section 744A(6)(A)(ii) of the FD&C Act. *See also* 21 CFR 207.1 (addressing drug establishment registration), stating that "[m]anufacture means each step in the manufacture, preparation, propagation, compounding, or processing of a drug," and indicating that "the term 'manufacture, preparation, propagation, compounding, or processing,' as used in section 510 of the Federal Food, Drug, and Cosmetic Act, includes relabeling, repackaging, and salvaging activities."

[37] Sections 510(b) and 510(i) of the FD&C Act. For information and instructions on the electronic registration process, please refer to FDA eDRLS Instruction webpage available at: https://www.fda.gov/drugs/drug-registration-and-listing-system-drls-and-edrls/electronic-drug-registration-and-listing-instructions.

[38] Section 510(p) of the FD&C Act; 21 CFR § 207.29

[39] https://www.fda.gov/industry/structured-product-labeling-resources/business-operation-qualifier.

[40] Section 744M(a)(1)(A) of the FD&C Act. See also section IV.E of this draft guidance, which addresses situations involving multiple manufacturing or processing sites.

B. Facility Fee for a CMO

A 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). CMO facilities will be assessed two-thirds of the amount of the fee paid by an MDF.

If a facility pays the facility fee for a CMO when the facility does not meet the definition of a CMO (i.e., the facility is an MDF), FDA will assess the difference in fees to the facility (i.e., the difference in fee amounts between the MDF and the CMO facility fees).

C. Facilities Not Eligible for Facility Fees Under OMUFA

The FDA does **not** assess OMUFA facility fees for facilities that do not meet the statutory definition of an "OTC monograph drug facility" as described in section III. Thus, no OMUFA facility fee will be assessed with respect to facilities that solely perform the following activities:

- manufacture or process human OTC drug products that are marketed under an application approved under section 505 of the FD&C Act or section 351 of the Public Health Service Act;
- manufacture or process human OTC drug products that are not governed by the provisions of section 505G of the FD&C Act (which addresses lawful marketing of certain nonprescription drugs absent an approved application);
- manufacture API ingredients that are intended to be included in subsequent manufacturing or processing.[41]
- manufacture or process the finished dosage form of an OTC monograph drug only for the production of clinical research supplies or testing;[42]
- engage in, as their only manufacturing or processing activity, 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.[43]
- For the purpose of this guidance, FDA considers "overpackaging" to be the enclosure of individual drug products that each bear full and complete labeling information required under the FD&C Act (e.g., Drug Facts Label[44] and Principal Display Panel[45]) and that could each be legally marketed independently, if not overpackaged and marketed as a set of such products.
    - For example, "overpackaging" may involve plastic shrink wrapping that encloses already packaged OTC monograph drug products that each bear complete labeling

[41] Section 744L(10)(A)(i)(II) of the FD&C Act. But see section IV of this draft guidance which explains when the manufacturer of API may be subject to a facility fee.
[42] Section 744L(10)(A)(iii).
[43] *Id.*
[44] See 21 CFR 201.66.
[45] See 21 CFR 201.60.

information (including Drug Facts Label and Principal Display Panel), as a set of such products for convenience or for "multipack" purposes such as first aid kits.

Consistent with the *Federal Register* notices (FRN) published by the Department of Health and Human Services (HHS) on January 12, 2021,[46] and by the FDA on March 26, 2021[47] and March 16, 2022,[48] 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),[49] *solely* for purposes of manufacturing hand sanitizer products[50] during the PHE.[51,52]

However, under the FD&C Act, whether an entity is subject to OMUFA fees has no bearing on whether the entity or the entity's products are subject to other requirements under the FD&C Act. FDA will continue to use its regulatory compliance and enforcement tools to protect consumers, including from potentially dangerous or subpotent hand sanitizers.

D. Exceptions to the Facility Fees

A facility fee will not be assessed for an OTC monograph drug facility for a fiscal year if the facility:

- has ceased all activities related to OTC monograph drugs prior to December 31 of the year preceding the applicable fiscal year, and
- has updated its registration within eDRLS to reflect such changes under the requirements for the drug establishment registration set forth in section 510 of the FD&C Act.[53]

For example, for FY 2021 (which began October 1, 2020), if an OTC monograph drug facility had ceased all activities related to OTC monograph drugs and updated its registration (e.g.,

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[46] *See* https://www.federalregister.gov/documents/2021/01/12/2021-00237/notice-that-persons-that-entered-the-over-the-counter-drug-market-to-supply-hand-sanitizer-during (86 FR 2420).

[47] *See* https://www.federalregister.gov/documents/2021/03/26/2021-06361/fee-rates-under-the-over-the-counter-monograph-drug-user-fee-program-for-fiscal-year-2021.

[48] *See* https://www.federalregister.gov/documents/2022/03/16/2022-05542/over-the-counter-monograph-drug-user-fee-rates-for-fiscal-year-2022.

[49] *See* https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx.

[50] The term "hand sanitizer" commonly refers to consumer antiseptic rubs. However, because the HHS *Federal Register* 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), FDA is 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. Use of the term "hand sanitizer products" 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.

[51] *See* 86 FR 2420. Facility fees would be assessed to entities that "manufacture, distribute, and sell over-the-counter drugs in addition to hand sanitizer" and entities that "continue to manufacture (as opposed to hold, distribute, or sell existing inventories) hand sanitizer products as of December 31 of the year immediately following the year during which the COVID-19 Public Health Emergency is terminated."

[52] For more information regarding hand sanitizers, please refer to FDA's COVID-19-Related Guidance Documents for Industry, FDA Staff, and Other Stakeholders webpage at https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders.

[53] Section 744M(a)(1)(B)(i) of FD&C Act.

delisted its OTC monograph drug products and deregistered the facility) within FDA's eDRLS prior to December 31, 2019, the FY 2021 facility fee was not assessed.

E. Fees for Multiple Locations or Relocations of the Same Entity

If an entity has multiple sites manufacturing or processing one or more OTC monograph drugs, and each site is in a different geographic location (including by relocation to a different geographic location during the relevant timeframe used for fee assessment),[54] each site is generally assessed a separate annual facility fee for the fiscal year at issue. However, separate buildings within close proximity are considered to be at one geographic location or address, for purposes of assessing a single facility fee, if:

- the activities in them are closely related to the same business enterprise;
- they are under the supervision of the same local management; *and*
- they are under a single FDA FEI and are capable of being inspected by FDA during a single inspection.[55]

These are the same criteria used by FDA's Office of Regulatory Affairs to evaluate whether separate FEIs are necessary for multiple facilities.[56] FDA utilizes its assignment of FEIs to help properly assess OMUFA facility fees in cases involving multiple locations of the same entity. FEI assignments are a designated data input when a person remits a facility payment through FDA's User Fee System.

If an entity believes that multiple FEIs have been assigned in error or that its separate facilities qualify for a single FEI, the entity may request consolidation of the FEIs. However, once a facility fee has been incurred for a fiscal year, the fee is not waived, reduced, or refunded if FDA subsequently agrees to consolidate FEI numbers for that fiscal year. The consolidated FEI numbers will be reflected in the following fiscal year user fee assessments.

Domestic entities should submit the request to the appropriate FDA district office. Contact information is available at http://www.fda.gov/downloads/ICECI/Inspections/IOM/UCM123522.pdf.

The FEI Search Portal[57] is available for facilities to look up an FEI number. The FEI Portal FAQs[58] provides additional information and resources on FEI.

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[54] Foreign or domestically located.

[55] Section 744L(10)(B) of the FD&C Act. Additionally, section 744L(10)(C) of the FD&C Act states that if a business or other entity would meet the definition of an OTC monograph drug facility under section 744L(10)(A) but for being under multiple management, the business or entity is deemed to constitute multiple facilities, one per management entity.

[56] An FEI number is issued by FDA to track inspections of the regulated establishment or facility. FEI numbers are also used to track OTC facility fee payments. An FEI number is different from a Central File Number and Federal Tax Identification Number.

[57] https://www.accessdata.fda.gov/scripts/feiportal/index.cfm?action=portal.login.

[58] https://www.accessdata.fda.gov/scripts/feiportal/index.cfm?action=common.faq.

F. Disputing an OMUFA Facility Fee

To qualify for the return of a facility fee claimed to have been paid in error, a person must submit to FDA a written request with justification for the return within 180 calendar days after the date such fee was paid (see Section VII.C. below).[59]

See Section VIII.A. below on how to request a refund or file a dispute request contesting FDA's user fee assessment.

G. Waivers and Reductions to OMUFA Facility Fees

Waivers and reductions to OMUFA facility fees are not authorized under the statute and thus not available. All companies pay the same applicable facility fee (i.e., MDF or CMO) regardless of size.

V. OTC MONOGRAPH ORDER REQUEST FEES

Under section 744M(a)(2) of the FD&C Act, the Agency is authorized to assess and collect fees from each person that submits an OMOR,[60] except for OMORs that request certain safety-related changes (as described in Section V.C).[61]

OMOR fees are due on the date of the submission of the OMOR (see Section VII.C. below).[62]

OMORs are separated into two categories: Tier 1 or Tier 2,[63] for which different fees apply.[64]

A. Tier 1 OMOR Fees

Tier 1 OMOR fees apply to any OMOR not determined to be a Tier 2 OMOR. Examples of Tier 1 OMORs include, but are not limited to, the addition of a new:

- ingredient to a monograph that already has one or more ingredients that have been found to be generally recognized as safe and effective (GRASE);
- 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;
- fixed-dose combination of ingredients to a monograph that already has one or more ingredients that have been found to be GRASE;

[59] Section 744M(a)(3)(B) of the FD&C Act. For the purposes of OMUFA fees, FDA considers the payment date to be the date on which the payment is received by FDA, not necessarily the date of payment submission.
[60] Section 744M(a)(2)(A) of the FD&C Act.
[61] Section 744M(a)(2)(C) of the FD&C Act.
[62] Section 744M(a)(2)(B) of the FD&C Act.
[63] A Tier 1 OMOR is defined as any OMOR that 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.
[64] Section 744M(a)(2)(A) of the FD&C Act.

- test method for a monograph that already has one or more ingredients that have been found to be GRASE, and the new test method applies to one or more of the GRASE ingredients;
- route of administration for a monograph that already has one or more ingredients that have been found to be GRASE, and the new route of administration applies to one or more of the GRASE ingredients;
- dose or concentration for a GRASE ingredient for a particular monograph; or
- monograph therapeutic category (each ingredient proposed for the new therapeutic category will be a separate OMOR).[65]

B. Tier 2 OMOR Fees

Tier 2 OMOR fees apply to Tier 2 OMORs, which are OMORs for[66]:

- reordering of existing information on the Drug Facts label;
- addition of information to the "Other Information" section of the Drug Facts label, as limited by 21 CFR 201.66(c)(7);
- modification to the Directions for Use section of the Drug Facts label, if such modification conforms to a final order under section 505G of the FD&C Act applicable to certain minor dosage form changes for the drug[67];
- the standardization of the concentration or dose of a specific finalized ingredient within a particular finalized monograph;
- a change to the ingredient nomenclature to align with the nomenclature of a standards-setting organization;
- the addition of an interchangeable term in accordance with 21 CFR 330.1(i); or
- any OMOR determined by the FDA to be a Tier 2 OMOR and published as such in a proposed order issued pursuant to section 505G of the FD&C Act.

C. Exceptions to the OMOR Fees

An OMOR fee will not be assessed if the OMOR seeks to make certain safety-related 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.[68]

[65] See page 10 of the document titled Over-the-Counter Monograph User Fee Program Performance Goals and Procedures - Fiscal Years 2018-2022 at https://www.fda.gov/media/106407/download.
[66] Section 744L(9) of the FD&C Act.
[67] See sections 744L(9)(A)(iii) and 505G(c)(3)(A) of the FD&C Act.
[68] Section 744M(a)(2)(C) of the FD&C Act.

D. OMOR Refused for Filing or Withdrawn

An OMOR fee is due and must be paid in full no later than the date of submission of the qualifying OMOR. If the requestor withdraws the OMOR *before* FDA accepted or refused the OMOR for filing or FDA refuses to file the OMOR, FDA will refund 75 percent of the OMOR fee to the payor.[69] A written refund request is not required.

If an OMOR is withdrawn *after* it is filed, FDA may refund the fee or a portion of the fee if no substantial work was performed on the OMOR. FDA has the sole discretion in determining whether to refund a fee or a portion of the fee to the requestor of the OMOR, including whether substantial work was performed on the filed OMOR. FDA's determination concerning a refund in these circumstances is generally not reviewable.[70]

An OMOR that was submitted but was refused for filing or was withdrawn before being accepted or refused for filing is subject to the full fee if the OMOR is resubmitted or filed over protest.[71]

E. OMOR Tier Recharacterization

If FDA determines that an OMOR initially characterized as Tier 1 shall be recharacterized as Tier 2, and the requestor has paid a Tier 1 fee, the difference between the Tier 1 and Tier 2 fees will be refunded.[72] In addition, the appropriate OMOR fee shall be refunded if FDA characterizes the OMOR involved to be an OMOR seeking certain safety-related changes for which an OMOR fee does not apply.[73] A written refund request is not required when the Agency recharacterizes an OMOR in either manner.

F. Disputing an OMOR Fee

To qualify for the return of an OMOR fee claimed to have been paid in error, a person must submit to FDA a written request with justification for the return of the OMOR fee within 180 calendar days after the date such fee was paid (see Section VII.C. below).[74]

See Section VIII.A. below on how to request a refund or file a dispute request contesting FDA's user fee assessment.

G. Waivers and Reductions to OMOR Fees

[69] Section 744M(a)(2)(E) of the FD&C Act.
[70] Section 744M(a)(2)(G) of the FD&C Act.
[71] Section 744M(a)(2)(F) of the FD&C Act.
[72] Section 744M(a)(2)(D) of the FD&C Act.
[73] Section 744M(a)(2)(C) of the FD&C Act.
[74] Section 744M(a)(3)(B) of the FD&C Act.

Waivers and reductions to OMOR fees are not authorized under the statute and thus not available.

VI. FAILURE TO PAY FEES

Failure to remit payment in full for user fees incurred pursuant to section 744M of the FD&C Act will result in certain penalties on an entity and/or its affiliates based on the type of fee, as described below. In addition, if payment of the fee is not received within 30 calendar days after the invoice is issued, such fee shall be treated as an obligation to the U.S. Government, and failure to pay fees may lead to collection activities by the Government pursuant to applicable laws.[75]

FDA is not required to notify requestors before refusing to receive an OMOR submission on the basis of unpaid fees.[76] Requestors are in the best position to monitor their business affiliates for compliance with OMUFA fee obligations. It is the requestor's responsibility to ensure that its user fee obligations, as well as those of its affiliates, are satisfied before submitting an OMOR.

A. Facility Fees

There are several consequences for failure to pay the facility fee:

- If the annual fee for a facility is not paid within 20 calendar days of the due date, as specified in section 744M(e)(1)(A) of the FD&C Act, the Agency will place the facility on a publicly available arrears list,[77,78] and all OTC monograph drug products produced at that facility or containing an ingredient manufactured at that facility are deemed misbranded under section 502(ff) of the FD&C Act;[79]
- If a person subject to a facility fee does not pay the facility fee, any OMOR submitted to FDA by such person is considered incomplete and will not be accepted for filing by FDA until all fees owed have been paid;[80] and
- If a person subject to a facility fee does not pay the facility fee, that person is ineligible for OTC monograph drug meetings until all fees owed have been paid.[81]

If an entity believes that a facility's appearance on the arrears list is in error, the entity should contact the Division of User Fee Management at CDERCollections@fda.hhs.gov and include supporting documentation as to why the entity believes the facility should not be included on the arrears list.

B. OMOR Fees

[75] Section 744M(g) of the FD&C Act.
[76] Section 744M(e)(2) of the FD&C Act.
[77] Section 744M(e)(1)(A)(i) of the FD&C Act.
[78] The publicly available arrears list is available within the User Fee Lists section of the OMUFA user fee website at: https://www.fda.gov/industry/fda-user-fee-programs/over-counter-monograph-user-fee-program-omufa
[79] Section 744M(e)(1)(A)(ii) of the FD&C Act.
[80] Section 744M(e)(2) of the FD&C Act.
[81] Section 744M(e)(3) of the FD&C Act.

If a person fails to remit the appropriate payment when submitting an OMOR, or is currently in arrears when submitting an OMOR, that OMOR shall be considered incomplete and shall not be accepted for filing until all fees owed are paid.[82] OTC monograph drug meeting requests from persons in arrears for OMOR fees will be denied or cancelled.[83]

VII. PAYMENT INFORMATION AND PROCEDURES

This section generally describes the process for payment of OMUFA fees. More detailed instructions for paying the fees can be found in the FDA OMUFA user fee website.[84] Additional instructions will be provided when the payor creates the OMUFA cover sheet using the FDA User Fee System.[85]

A. Payment Procedures for OMUFA Fees

- Those responsible for payment of fees enter the required information on FDA's User Fee System[86] to generate an OMUFA cover sheet.
- The cover sheet is designed to provide the minimum necessary information to determine if a person has satisfied all relevant user fee obligations.
- The cover sheet is submitted to FDA electronically, generating a user fee identification (ID) number to assist in tracking payment.

One entity may pay OMUFA fees on behalf of another entity. Those paying fees are responsible for determining all financial institution transaction fees that may be deducted from an entity's authorized amount for payment to FDA. These include wire transfer and foreign exchange fees. Fee payors must ensure that the net amount paid to FDA is the full amount owed.

B. Acceptable Forms of Payment

Payment must be made in U.S. currency using U.S. bank accounts as well as U.S. credit cards. Payment must be 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).[87]

C. Timely Payment of Fees

FDA's expectation is for a timely and full payment of all OMUFA fees. For penalties associated with nonpayment by the fees due date, see Sections VI.A. and VI.B.

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[82] Section 744M(e)(2) of the FD&C Act.
[83] Section 744M(e)(3) of the FD&C Act.
[84] https://www.fda.gov/industry/fda-user-fee-programs/over-counter-monograph-user-fee-program-omufa
[85] https://userfees.fda.gov/OA_HTML/omufaCAcdLogin.jsp
[86] https://userfees.fda.gov/OA_HTML/omufaCAcdLogin.jsp
[87] https://www.federalregister.gov/documents/2022/03/16/2022-05542/over-the-counter-monograph-drug-user-fee-rates-for-fiscal-year-2022

OMUFA fee payments should be made in a timely manner to meet the required facility fee payment due date or be paid upon submission of an OMOR. FDA records, as the receipt date of an OMOR submission, the later of the following:

- the date the OMOR submission is received by FDA; or
- the date FDA receives payment for the submitted OMOR.

D. Nonpayment of OMUFA Fees

Delinquent entities will receive an invoice from FDA detailing information on the user fee incurred, the due date, and the payment instructions.

If full payment is not received by the date specified on the invoice, interest will be charged at a rate set by the U.S. Department of Treasury. In addition, delinquent invoices will have a $20 administrative fee assessed for each 30-day period that the invoice remains outstanding. A penalty of 6 percent per year will be assessed on any invoice delinquent for more than 90 days in accordance with 45 CFR 30.18.

VIII. REFUNDS, DISPUTES CONCERNING FEES, AND APPEAL PROCESS

A. Refunds and Disputes Concerning Fees Request

A person may submit a written request to FDA requesting the return of the fees claimed to have been paid in error or otherwise disputing FDA's user fee assessment.[88] The permissible grounds for a refund are discussed in more detail in section 744M(a)(3) of the FD&C Act. The request justifying the return of the fee or disputing FDA's user fee assessment must be submitted within 180 calendar days after the date such fee was paid.[89] Note that if a written request is not made within 180 calendar days after the date such fee was paid, no return of fees is permitted. A written request and a completed Form FDA 3913[90] are to be submitted to the Division of User Fee Management at CDERCollections@fda.hhs.gov.

B. Reconsideration Request

If FDA fully or partially denies an entity's request for a refund or reduction[91] of user fees, the entity may request reconsideration of that decision. A request for reconsideration should be made within 30 calendar days of the issuance of FDA's decision to fully or partially deny a request for refund or reduction of user fees.

FDA recommends that requests for reconsideration state the entity's reasons for believing that FDA's decision is in error and include any additional information that is relevant to the entity's

[88] Section 744M(a)(3).
[89] Section 744M(a)(3)(B) of the FD&C Act.
[90] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM492188.pdf.
[91] A fee reduction may occur if the FDA reclassifies (a) an OMOR from Tier 1 to Tier 2, (b) an OMOR from Tier 1 or Tier 2 to an OMOR which requests certain safety-related changes such that the OMOR is fee-exempt, or (c) an MDF to a CMO.

position. The Agency will issue a response upon reviewing the reconsideration request, setting forth the basis for the decision.

All requests for reconsideration are to be submitted via email to CDERCollections@fda.hhs.gov and are to be addressed to the following:

Division of User Fee Management
Attention: Division Director
Center for Drug Evaluation and Research

In instances where an entity is unable to submit an electronic request, the entity can mail the request to FDA via the carrier of its choice. For the most updated mailing address, visit the following FDA website: https://www.fda.gov/industry/fda-user-fee-programs/over-counter-monograph-user-fee-program-omufa.

C. Appeal Request

If a request is denied upon reconsideration, the entity may choose to appeal the denial. A request for an appeal should be made within 30 calendar days of the issuance of FDA's decision to affirm its denial of a request for a refund or reduction of user fees. All of the following information should be included in the appeal:

- the original request
- the denial of the original request
- the reconsideration request
- the denial of the reconsideration request
- a statement of the entity's reasons for believing that the prior conclusions were in error

No new information or new analyses are to be presented in the appeal request. If new information or analyses are presented in the appeal request, the appeal will not be accepted, and the matter will be referred back to the original deciding authority to consider the new information or analyses.

All requests for appeals should be submitted to the Director of CDER's Office of Management via CDERCollections@fda.hhs.gov, and a copy should be submitted to the CDER Formal Dispute Resolution Project Manager. The contact information can be found on the CDER Formal Dispute Resolution web page.[92] Alternatively, an entity can mail the request to FDA via the carrier of the entity's choice. For the most updated mailing address, visit the following FDA website: https://www.fda.gov/industry/fda-user-fee-programs/over-counter-monograph-user-fee-program-omufa.

After FDA reviews the information submitted in the appeal request, the Director of CDER's Office of Management will issue a written decision on the entity's request.

[92] https://www.fda.gov/about-fda/cder-contact-information/cder-formal-dispute-resolution

If the entity's appeal is denied at one management level, the entity can appeal the same matter to the next higher management level in the CDER chain of command. A new request should be submitted for each appeal to the next management level and should follow the process provided in this guidance. If the entity has exhausted CDER's management levels and remains unsatisfied with the decision, the entity may request review of the matter by the Commissioner of Food and Drugs (Commissioner) under 21 CFR 10.75(c). Requests for review by the Commissioner should be submitted to FDA's Ombudsman, with copies provided to CDER. Review of such matters by the Commissioner is discretionary.[93]

IX. OTHER RESOURCES

The following documents may be helpful:

- CDER, Office of New Drugs (OND), Office of New Drugs Clinical (ONDC), Office of Nonprescription Drug (ONPD) Webinar, *Monograph reform is here! Learn what to expect and how to prepare* (May 29, 2020), available at: https://www.fda.gov/drugs/news-events-human-drugs/webinar-monograph-reform-here-learn-what-expect-and-how-prepare-05292020-05292020
- *Federal Register* notice, *Fee Rates Under the Over-the-Counter Monograph Drug User Fee Program for Fiscal Year 2021* (March 26, 2021), available at: https://www.federalregister.gov/documents/2021/03/26/2021-06361/fee-rates-under-the-over-the-counter-monograph-drug-user-fee-program-for-fiscal-year-2021
- Over-the-Counter (OTC) Drug Monograph Process website, https://www.fda.gov/drugs/over-counter-otc-drug-monograph-process
- Over-the-Counter Monograph User Fee Program Performance Goals and Procedures - Fiscal Years 2018-2022, https://www.fda.gov/media/106407/download
- Over-the-Counter Monograph User Fee Program Performance Goals and Procedures Table II.J.3: Summary of Dates of Specified Activities under OMUFA Fiscal Years 2021-2025, https://www.fda.gov/media/146283/download
- Over-The-Counter Monograph User Fee Program (OMUFA) website, https://www.fda.gov/industry/fda-user-fee-programs/over-counter-monograph-user-fee-program-omufa
- User Fee Payment Refund Request, FDA Form 3913, https://www.fda.gov/media/96650/download
- User Fees Payment Portal, https://userfees.fda.gov/OA_HTML/omufaCAcdLogin.jsp

[93] See 40 FR 40682 at 40693 (September 3, 1975); see 21 CFR 10.75.