Over-The-Counter Monograph User Fee Program (OMUFA)

Latest News

The FY 2021 Over-The-Counter Monograph Drug User Fee Program (OMUFA) facility fee invoices were emailed on June 25, 2021, to those facilities that have not satisfied their OMUFA user fee(s) as required under section 744M of the FD&C Act, as added by the Coronavirus Aid, Relief, and Economic Security Act.

On June 14, 2021, FDA, in accordance with section 744M(e)(1)(A) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), published an arrears list for those facilities that have not satisfied the Over-The-Counter Monograph User Fee Program (OMUFA) facility fee(s) as required under section 744M of the FD&C Act, as added by the Coronavirus Aid, Relief, and Economic Security Act. The arrears list is available to the public in the User Fee Lists section of this webpage. FDA plans to periodically update the arrears list to reflect facility payments.

FDA updated and reissued the rates for over-the-counter (OTC) monograph Drug User Fees for fiscal year (FY) 2021 in a Federal Register Notice (FRN) titled "*Fee Rates under the Over-The-Counter Monograph Drug User Fee Program for Fiscal Year 2021*." This FRN announced fees established under the Federal Food, Drug, and Cosmetic (FD&C) Act with respect to OTC monograph drug facilities and OTC Monograph Order Requests (OMORs) for FY 2021. OTC monograph drug facility fees for FY 2021 were due on May 10, 2021. FDA also posted an FDA-In-Brief about this action.

Fiscal Year (FY) 2021 User Fee Rates

FY 2021 Facility User Fee Rates

Monograph Drug Facility (MDF) Facility Fee	$20,322
Contract Manufacturing Organization (CMO) Facility Fee	$13,548

FY 2021 OMOR Fee Rates

Tier 1	$500,000
Tier 2	$100,000

Background and Legislation

On March 27, 2020, "the Coronavirus Aid, Relief, and Economic Security Act" (or the "CARES Act") was signed into law. Division A of the CARES Act includes an

important legislative initiative, detailed in subtitle F of title III, that reforms and modernizes the way certain nonprescription, over-the-counter (or OTC) drugs are regulated in the United States. These drugs, known as OTC monograph drugs, may be marketed without an approved drug application under section 505 of the Federal Food, Drug, and Cosmetic (FD&C Act) if they meet the requirements of section 505G of the FD&C Act, as well as other applicable requirements. Under this OTC monograph reform legislation, FDA will also assess and collect user fees dedicated to OTC monograph drug activities.

The new user fee program, which we refer to as the Over-the-Counter Monograph User Fee Act (or "OMUFA"), is modeled after the successful Prescription Drug User Fee Act (PDUFA). For OMUFA purposes, industry-paid fees will help fund a portion of FDA's regulatory activities for OTC monograph drugs and FDA agreed to adhere to performance goals, including to review submissions within specific time frames. As with PDUFA, FDA anticipates that this user fee program will provide additional resources to help the agency conduct these important regulatory activities in a timely manner and ultimately help provide the public with access to innovative OTC monograph drugs.

OMUFA is authorized under sections 744L and 744M of the FD&C Act, as added by the CARES Act, under which FDA will assess and collect fees from submitters of OTC Monograph Order Requests (OMORs), other than OMORs for certain safety changes, as well as from qualifying manufacturers of OTC monograph drugs, to help fund the agency's OTC monograph drug activities.

Federal Register Documents

- FR Notice March 26, 2021: *Fee rates under the Over-The-Counter Monograph Drug User Fee Program for Fiscal Year 2021*
- FR Notice Over-the-Counter Monograph User Fees: August 23, 2017 Stakeholder Meeting
- FR Notice Over-the-Counter Monograph User Fees: Reopening of Comment Period; Sept 6, 2016 Stakeholder Meeting
- FR Notice announcing June 10, 2016 public meeting: Over-the-Counter Monograph User Fees

OTC Monograph

What is an OTC monograph drug?

An OTC monograph drug is a nonprescription, over-the-counter (or OTC) drug that may be marketed without an approved 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.

What is an OTC monograph?

Simply stated, an OTC monograph is a "rule book" for each therapeutic category establishing conditions, such as active ingredients, uses (indications), doses, route of

administration, labeling, and testing under which an OTC drug is generally recognized as safe and effective (GRASE).

What was the OTC Drug Review prior to enactment of the "Coronavirus Aid, Relief, and Economic Security Act" (CARES Act)?
In 1972, FDA established the Over the Counter (OTC) Drug Review to evaluate the safety and effectiveness of nonprescription, OTC drug products marketed in the United States before May 11, 1972. The OTC Drug Review established conditions under which OTC drugs were generally recognized as safe and effective (GRASE) and not misbranded. These GRASE conditions were described in OTC drug monographs for each OTC therapeutic drug class. Prior to enactment of the CARES Act, the OTC Drug Review relied on a three-phase public rulemaking process to establish monographs.

For more information on the OTC Drug Review prior to enactment of the CARES Act, see the FDA webinar titled Monograph reform is here! Learn what to expect and how to prepare.

How does the CARES Act reform the OTC Drug Review?
The CARES Act, enacted on March 27, 2020, includes important reforms that modernize the way OTC monograph drugs are regulated in the United States. Specifically, the CARES Act replaces the rulemaking process with an administrative order process for issuing, revising, and amending OTC monographs. The CARES Act also provides FDA the authority to assess and collect user fees dedicated to OTC monograph drug activities. FDA anticipates that this user fee program will provide additional resources to help the agency conduct these important regulatory activities in a timely manner and ultimately help provide the public with access to innovative OTC monograph drugs.

Why did the OTC Drug Review need to be reformed?
Despite FDA's successes in providing consumers with access to a wide variety of safe and effective OTC monograph drugs, challenges with the nearly 50-year old OTC Drug Review process became apparent. The biggest challenges of the OTC Drug Review prior to the CARES Act included:

- Burdensome, multistep rulemakings to establish or amend monographs;
- FDA lacked adequate resources to devote to rulemaking process;
- Delays in finalizing monographs;
- Limited, burdensome process for innovation (e.g., new combinations of ingredients or new dosage forms);
- Delays in responding to safety issues; and
- Challenges in keeping pace with evolving science and changing market conditions.

What will OTC Monograph Reform provisions in the CARES Act accomplish?
OTC Monograph Reform is expected to accomplish the following:

- Improve the process by replacing rulemaking with administrative orders;
- Improve efficiency, timeliness, and predictability;

- Facilitate innovation;
- Establish a process to rapidly address safety issues;
- Finalize pending monographs; and
- Provide FDA with user fees to support OTC monograph drug activities.

Are there timelines and performance goals for OTC Monograph Reform under the CARES Act?
Yes, the Over-the-Counter Monograph User Fee Program Performance Goals and Procedures document outlines the performance and procedural goals and other commitments agreed to by the agency for purposes of this user fee program. These goals apply to aspects of the over-the-counter monograph drug review program that are important for facilitating timely access to safe and effective medicines regulated under the OTC drug monograph system, and to implementing the OTC monograph policy reforms.

During the first three years of OTC Monograph Reform, essentially all effective review capacity is expected to be consumed by current external mandates, safety activities, and OTC Monograph Reform implementation and infrastructure development activities. Beginning in Years 4 and 5 (and to a limited extent in Year 3), FDA expects to have built sufficient effective review capacity to begin to have timelines and performance goals for review activities expected to be part of the steady state of a monograph review program.

FDA is committed to meeting the timelines and performance goals and to continuous improvement of its performance.

What are the types of user fees under OMUFA?
FDA will collect two types of user fees under OMUFA:

1. Facility fees
2. OTC Monograph Order Request (OMOR) fees

When will OMUFA fees be due for fiscal years after FY 2021?
For fiscal years after FY 2021, OMUFA facility fees will be due on the later of (a) the first business day of June of each year or (b) the first business day after the enactment of an appropriations act providing for the collection and obligation of OMUFA fees for such year, as described in section 744M(a)(1)(D)(ii) of the FD&C Act. The facility fee amounts will be set in advance of the due date through a Federal Register Notice, in accordance with the process specified under the statute.

Fees for OTC monograph order requests (OMORs) are due on the date of submission of the OTC monograph order request, as stated in section 744M(a)(2)(B) of the FD&C Act.

Do large companies and small companies pay different fees?
No, all companies pay the same applicable fee (i.e., facility and/or OMOR), regardless of size.

Does paying user fees for other user fee programs (like PDUFA, GDUFA, or MDUFA) negate the need to pay over-the-counter drug user fees?
No. Payment of user fees under the Prescription Drug User Fee Act (PDUFA), Generic Drug User Fee Amendments (GDUFA), Medical Device User Fee Act (MDUFA), or other user fee programs does not negate the need to pay OMUFA fees. For example, if you already pay prescription drug user fees under PDUFA and are also a qualifying person who owns an over-the-counter (OTC) monograph drug facility, you would need to pay an OMUFA facility fee. Additionally, each person that submits a qualifying over-the-counter (OTC) monograph order request (OMOR) is required to pay the OMOR fee at the time of submission.

For more information on these fees, please see the "Facility Fees" and "OTC Monograph Order Request (OMOR) Fees" sections on this webpage.

How are fees paid?
Information about fee payment options and procedures can be found in the Federal Register Notice published on March 26, 2021, "*Fee rates under the Over-The-Counter Monograph Drug User Fee Program for Fiscal Year 2021*."

Facility Fees

Who pays the OMUFA facility fee?
The facility fee will be assessed for qualifying persons who own an OTC monograph drug facility, including contract manufacturing organization facilities.

The OTC Monograph User Fee program does not assess a facility fee for human OTC drug products that are produced under an approved drug application. The Federal Register Notice referenced above will provide more information about FY 2021 facility fees.

When is the facility fee due?
The facility fee is due annually.

When are OMUFA facility fees due for FY 2021?
OTC monograph drug facility fees for FY 2021 are due 45 calendar days after March 26, 2021, on May 10, 2021

What is an OTC monograph drug facility?
Under section 744L of the FD&C Act, an OTC monograph drug facility is generally defined as a foreign or domestic business or other entity that:

1. is under one management, either direct or indirect, and at one geographic location or address engaged in manufacturing or processing the finished dosage form of an OTC monograph drug;
2. 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
3. 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 contained within the overpackaging is already in a final packaged form prior to placement in the outer overpackaging.

What is an OTC monograph drug contract manufacturing organization (CMO) facility?
As defined in section 744L of the FD&C Act, a CMO facility is 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.

Are these CMO facilities required to pay a facility fee?
Yes, a qualifying CMO facility pays a fee equal to two-thirds of the amount of the fee for a qualifying **OTC monograph drug facility that is not a CMO facility.**

How were OTC monograph drug facility fees for FY 2021 calculated?
The statute mandates that facility fee rates shall be established to generate a calculated total facility revenue amount, which for FY 2021 is equal to $23,269,000 (rounded to the nearest thousand dollars). FDA determined the number of OTC monograph drug facilities subject to a facility fee using data from the Electronic Drug Registration and Listing System (eDRLS). FDA then calculated the per facility fee in accordance with the statute, based on the number of each type of facility and other relevant factors, and consistent with a clarification in the Department of Health and Human Services' January 12, 2021, Federal Register Notice.

More information about the calculation of FY 2021 facility fees can be found in the Federal Register Notice published on March 26, 2021, "*Fee rates under the Over-The-Counter Monograph Drug User Fee Program for Fiscal Year 2021*."

Does the FY 2021 OMUFA facility fee apply to facilities that manufacture or process hand sanitizer products under the temporary policy during COVID-19?
No. Consistent with the Department of Health and Human Services' (HHS) Notice published on January 12, 2021, 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 OTC hand sanitizer products during the PHE.

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 sub-potent hand sanitizers.

Will the facility fee be assessed per product listing submitted (label), one fee per formula, or one per facility?
The annual facility fee is assessed "per facility," in accordance with the definition of an OTC monograph drug facility, as set forth in section 744L(10) of the FD&C Act, and the authority for facility fees under section 744M of the FD&C Act. As defined in the statute, an OTC monograph drug facility means 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. OTC monograph drug facilities can include a contract manufacturing organization (CMO) facility (see section 744L(10) of the FD&C Act). 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).

Does the FY 2021 OMUFA facility fee apply to my facility?
The FD&C Act specifies which facilities are subject to an OMUFA fee. As stated above, the OMUFA FY 2021 facility fee applies to facilities meeting the FD&C Act definition of an OTC monograph drug facility, in addition to other criteria, as described in the Federal Register Notice "*Fee rates under the Over-The-Counter Monograph Drug User Fee Program for Fiscal Year 2021*" issued on March 26, 2021. Further, FD&C Act section 744M(d) requires each person that owns an OTC monograph drug facility to submit information about the facility's business operation as such as part of annual establishment registration under FD&C Act section 510.

The FY 2021 OMUFA facility fee does not apply to the facilities and entities detailed below:

- those facilities that only manufacture the active pharmaceutical ingredient (or API) of an OTC monograph drug do not meet the definition of an OTC monograph drug facility (see section 744L(10)(A)(i)(II);
- OTC monograph drug facilities that had ceased all activities related to OTC monograph drugs prior to December 31, 2019 and had updated their registration with FDA to reflect that change (see section 744M(a)(1)(B)(i) of the FD&C Act); or
- entities that 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.

I received a fee notice, but I don't think my facility should be charged an OMUFA facility fee for FY 2021. What should I do?
If you believe your facility is not an OTC monograph drug facility as described in this Notice and should not be assessed an OMUFA FY 2021 facility fee, please contact CDERCollections@fda.hhs.gov.

Does the FRN posted on March 26, 2021 replace the FRN of the same name that was published on December 29, 2020? How do they differ?
Yes, the FRN posted on March 26, 2021 replaces an FRN of the same title published on December 29, 2020, which was withdrawn by the Department of Health and Human Services (HHS) on January 6, 2021. Today's updated FRN includes:

- Notification that, consistent with an HHS January 12, 2021 Notice, 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 to manufacture OTC hand sanitizer during the PHE; and

- Updates to the fee amounts.

The Agency recognizes that because certain hand sanitizer product facilities will not pay fees, the facility fees for the remaining payors have increased for FY 2021, since the number of manufacturers subject to OMUFA facility fees has decreased.

What is an FDA Establishment Identification number?
An FDA Establishment Identification (FEI) number is a unique identifier issued by FDA to track inspections of the regulated establishment or facility. FEI numbers are also used to track OTC facility fee payments. Please note that an FEI number is different from a Central File Number and Federal Tax Identification Number. As stated in section 744L(4) of the FD&C Act, FEIs are automatically generated by FDA's Field Accomplishments and Compliance Tracking System (FACTS) (or any successor system).

OTC Monograph Order Request (OMOR) Fees

What is an administrative order for an OTC monograph?
The CARES Act gives FDA the authority to issue an administrative order that adds, removes or changes GRASE conditions for an OTC drug monograph.

Who can initiate an administrative order?
Either industry or FDA can initiate the administrative order process. A request by industry to initiate the administrative order process is called an OTC Monograph Order Request (OMOR) and can be made by a requestor, which is defined in the CARES Act as any person or group of persons marketing, manufacturing, processing, or developing a drug.

Are administrative orders publicly available?
As FDA issues each proposed or final administrative order, FDA will publish the order on FDA's public website. Additionally, FDA will also publish a Notice of Availability of each proposed and final administrative order in the Federal Register.

Can the public comment on proposed administrative orders? How?
Yes. After issuance of a proposed administrative order, there will be a public comment period. The public will receive at least 45 calendar days (and potentially longer depending on the subject of the proposed order) to submit comments on the proposed administrative order. When FDA issues the proposed order, the agency will provide Information on how the public should submit their comments and the duration of the comment period.

When can FDA expedite an administrative order?
The procedure for FDA to initiate an administrative order can be expedited when FDA determines:

- a drug poses an imminent hazard to public health; or
- a change in the labeling of a drug, class of drugs, or combination of drugs is reasonably expected to mitigate a significant or unreasonable risk of a serious adverse event associated with use of the drug.

What is an OTC monograph order request (OMOR)?
The term "OTC monograph order request" (or OMOR) is defined in section 744L(7) of the FD&C Act and refers to a request for FDA to issue an administrative order under section 505G of the FD&C Act.

There are two types of OMORs: Tier 1 and Tier 2.

As described in section 744L(8) of the FD&C Act, a Tier 1 OMOR is any request not determined to be a Tier 2 OMOR.

Examples of Tier 1 OMORs include additions of:

1. A new ingredient to a monograph that already has one or more ingredients that have been found to be GRASE.
2. 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.
3. New monograph therapeutic category (each ingredient proposed for the new therapeutic category will be a separate OMOR).

As described in section 744L(9) of the FD&C Act, a Tier 2 OMOR is a request for:

1. Reordering of existing information in the drug facts label of an OTC monograph drug;
2. Addition of information to the "Other Information" section of the drug facts label of an OTC monograph drug (subject to certain limitations);
3. Modification to the "Directions for Use" section of the drug facts label of an OTC monograph drug, consistent with a minor dosage form change;
4. Standardization of the concentration or dose of a specific finalized ingredient within a particular finalized monograph;
5. Change to ingredient nomenclature to align with nomenclature of a standards-setting organization; or
6. Addition of an interchangeable term in accordance with section 330.1 of title 21, Code of Federal Regulations (or any successor regulations).

Based on program implementation experience or other factors found appropriate by FDA, FDA may also characterize any OMOR as a Tier 2 OMOR (including recharacterizing a request from Tier 1 to Tier 2) and publish such determination in a proposed order issued pursuant to section 505G of the FD&C Act.

Who pays an OMOR fee?
As described in section 744M(a) of the FD&C Act, beginning with FY 2021, each person that submits an OMOR is subject to an OMOR fee upon submission of the OMOR. However, a person that submits an OMOR shall not be subject to an OMOR fee 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—

- (i) a contraindication, warning, or precaution;
- (ii) a statement about risk associated with misuse or abuse; or

- (iii) an instruction about dosage and administration that is intended to increase the safe use of the OTC monograph drug.

When are OMOR fees due for FY2021?
Each person that submits an OMOR is subject to an OMOR fee upon submission of the OMOR.

However, a person that submits a certain type of safety-related OMOR shall not be subject to an OMOR fee. Specifically, under the statute, no OMOR 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—

- (i) a contraindication, warning, or precaution;
- (ii) a statement about risk associated with misuse or abuse; or
- (iii) an instruction about dosage and administration that is intended to increase the safe use of the OTC monograph drug.

How will OMOR fees for FY 2022 be calculated?
Sections 744M(a)(2)(A)(i) and 744M(a)(2)(A)(ii) of the FD&C Act specify that the FY 2022 OMOR fees for Tier 1 and 2 OMORs, respectively, will be $500,000 and $100,000, adjusted for inflation for the fiscal year.

Meetings

How do I request a formal meeting with FDA?
FDA will develop guidance regarding formal meetings between FDA and sponsors or requestors of OMORs, as required by section 505G(l) of the FD&C Act. Prior to publication of that guidance, submit meeting requests to Monograph-Meeting-Requests@fda.hhs.gov. FDA anticipates such guidance will include guidance on the content of a meeting package for formal meetings between FDA and sponsors or requestors of OMORs. Prior to publication of this guidance, meeting requestors can refer to the guidance for industry *Formal Meetings Between the FDA and Sponsors and Applicants of PDUFA Products*. Meeting package content questions that are not covered in this guidance can be addressed to Monograph-Meeting-Requests@fda.hhs.gov.

Additional information on the types of meetings and overall process for meetings can be found in the Over-the-Counter Monograph User Fee Program Performance Goals and Procedures document.

When can sponsors and requestors begin requesting formal meetings?
Sponsors and requestors may submit meeting requests at any time. Sponsors and requestors may submit meeting requests to Monograph-Meeting-Requests@fda.hhs.gov.

User Fee Lists

- Other OMUFA Fee-Related Questions
- OMUFA Facility Arrears List (PDF - 218 KB)
- OMUFA Facility Arrears List (XLSX - 42 KB)

Related Information

- June 3, 2021 OTC Monograph Drug User Fee Program (OMUFA): Understanding FY 2021 User Fees Webinar
- Over-the-Counter (OTC) Drug Review | OTC Monograph Reform in the CARES Act
- March 25, 2021 FDA In Brief: FDA Republishing Fee Rates under the Over-the-Counter Monograph Drug User Fee Program
- August 6, 2020 FDA Voices : An Exciting New Chapter in OTC Drug History: OTC Monograph Reform in the CARES Act
- "Monograph Reform is Here" webinar presentation from May 29, 2020
- Over the Counter Monograph User Fees Program Performance Goals and Procedures
  Dates of commitments will be updated to reflect the date of passage of the legislation
    - Updated Over-the-Counter Monograph User Fee Program Performance Goals Dates– Fiscal Years 2021-2025: FDA has updated the dates to be used for purposes of the *Over-the-Counter Monograph User Fee Program Performance Goals and Procedures* (OMUFA goals letter) to reflect that FY 2021 is the first program year, per the statutory authority for OMUFA fees enacted under the Coronavirus Aid, Relief, and Economic Security (CARES) Act. This updating aligns with language in the OMUFA goals letter stating that although it was drafted under the assumption that FY 2018 would be the first program year, "*If the program has a different effective date, goal dates…will need to be adjusted accordingly*." The updated goal dates in this document should be referred to in place of the "*Summary of Dates of Specified Activities under OMUFA*" table on pages 34-37 of the OMUFA goals letter.
- September 6, 2016 Stakeholder Webinar – Meeting Summary
- FDA and Industry Discussions
- June 10, 2016 public meeting: Over-the-Counter Monograph User Fees
- Frequently Asked Questions on Potential OTC Monograph User Fee Program
- OTC Drug Monograph Process
- Over-the-Counter (OTC) | Nonprescription Drugs
- User Fees

Contact Us

- **Questions for the Over-the-Counter Monograph Drug User Fee staff**? Email CDERCollections@fda.hhs.gov or call 301-796-7900.
- **Questions about refunds**? Email CDERCollections@fda.hhs.gov.
- **Questions about making a payment or confirming the status of a payment**? Email the User Fee Helpdesk at userfees@fda.gov or call 301-796-7200.
- **Questions about Pay.gov**? Email pay.gov.clev@clev.frb.org or call 800-624-1373.
- **Questions about registration and listing of drug products**? Email the eDRLS team at edrls@fda.hhs.gov.