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 each fiscal year?

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 published in advance of the due date through a *Federal Register* notice.

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 OMOR fee payment procedures can be found in the *Federal Register* notice, "Over-the-Counter Monograph Drug User Fee Program – OTC Monograph Order Requests Fee Rates for Fiscal Year 2024" issued in September 2023."

Information about facility fee payment procedures can be found in the *Federal Register* notice issued in March 2024, "Over-the-Counter Monograph Drug User Fee Program – Facility Fee Rates for Fiscal Year 2024."

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 Drug 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 provides more information about FY 2024 facility fees.

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

When are OMUFA facility fees due for FY 2024?
OTC monograph drug facility fees for FY 2024 are due on Monday June 3, 2024.

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 2024 calculated?

The statute mandates that facility fee rates shall be established to generate a calculated total facility revenue amount, which for FY 2024 is equal to $32,253,000 (rounded to the nearest thousand dollars). FDA calculated the number of fee-liable OTC monograph drug facilities of each type (MDF and CMO) using data that included registrations from the Electronic Drug Registration and Listing System (eDRLS) and the breakdown of facilities that paid FY 2023 OMUFA facility fees, in addition to other information. FDA calculated the per-facility fee based on the number of each type of facility and other relevant factors and assumptions.

More information about the calculation of FY 2024 facility fees can be found in the *Federal Register* notice issued on March 29, 2024, "Over-The-Counter Monograph Drug User Fee Rates for Fiscal Year 2024"

Why did facility fees increase in FY 2024?

In calculating the facility fee rates for each fiscal year, in accordance with our statutory authority, FDA bases its calculations on factors that include the 1) number of fee-liable facilities, 2) ratio of Monograph Drug Facilities (MDF) to Contract Manufacturing Organizations (CMO), and 3) increases in the total target revenue due to inflation and other adjustments.

This year's facility fee reflects an increase of 31% compared to the FY 2023 fee amount. This increase is largely due to the additional dollar amount of $7 million (as specified in the statute) used to determine the FY 2024 target revenue to be generated from facility fees, pursuant to the statutory calculations. Please see the FRN titled "Over-the-Counter Monograph Drug User Fee Program – Facility Fee Rates for Fiscal Year 2024" for the methodology utilized in calculating OMUFA facility fee rates for FY 2024.

Does the FY 2024 OMUFA facility fee apply to facilities that only manufactured or processed hand sanitizer products during the COVID-19 public health emergency?

No. Consistent with the Department of Health and Human Services' (HHS) Notice published on January 12, 2021, and FDA's OMUFA fee rate notices for FYs 2021-2023, FDA will not assess OMUFA facility fees for FY 2024 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.

However, the agency is highlighting in its March 29, 2024 Federal Register Notice titled "Over-the-Counter Monograph Drug User Fee Program – Facility Fee Rates for Fiscal Year 2024" the following information for stakeholders in the interest of transparency regarding the agency's planning for assessment of OMUFA facility fees for FY 2025: the January 12, 2021, HHS Federal Register notice (FRN) explains that "[t]he Department's conclusion [that certain hand sanitizer manufacturers are not identified as OTC Monograph Drug facilities] does not apply to such persons which (1) manufacture, distribute, and sell over-the-counter drugs in addition to hand sanitizer or (2) *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. In those cases, the Department may identify such persons as OTC drug manufacturing facilities*." Accordingly, as the PHE expired on May 11, 2023, those facilities that "continue to manufacture" solely hand sanitizer products as of December 31, 2024 will be identified as OTC monograph drug facilities and be subject to an OMUFA facility fee for FY 2025. Conversely, if such facilities cease manufacturing hand sanitizer products and delist and deregister to reflect that before 12:00 am EST on December 31, 2024, they

will not be identified as an OTC monograph drug facility and will not be considered fee liable for purposes of FY 2025 OMUFA facility fees.

Does the FY 2024 OMUFA facility fee apply to my facility?
The FD&C Act defines which facilities are subject to an OMUFA fee. As stated above, the OMUFA FY 2024 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 "Over-the-Counter Monograph Drug User Fee Program – Facility Fee Rates for Fiscal Year 2024" issued on March 29, 2024. 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 part of annual establishment registration under FD&C Act section 510.

The FY 2024 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, which do not meet the definition of an OTC monograph drug facility under section 744L(10)(A)(i)(II) of the FD&C Act
- OTC monograph drug facilities that had ceased all activities related to OTC monograph drugs prior to December 31, 2021, 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 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.

The agency is highlighting in its March 29, 2024 *Federal Register* Notice titled "Over-the-Counter Monograph Drug User Fee Program – Facility Fee

Rates for Fiscal Year 2024" the following information for stakeholders in the interest of transparency regarding the agency's planning for assessment of OMUFA facility fees for FY 2025: the January 12, 2021, HHS Federal Register notice (FRN) explains that "[t]he Department's conclusion [that certain hand sanitizer manufacturers are not identified as OTC Monograph Drug facilities] does not apply to such persons which (1) manufacture, distribute, and sell over-the-counter drugs in addition to hand sanitizer or (2) *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. In those cases, the Department may identify such persons as OTC drug manufacturing facilities*." Accordingly, as the PHE expired on May 11, 2023, those facilities that "continue to manufacture" solely hand sanitizer products as of December 31, 2024 will be identified as OTC monograph drug facilities and be subject to an OMUFA facility fee for FY 2025. Conversely, if such facilities cease manufacturing hand sanitizer products and delist and deregister to reflect that before 12:00 am EST on December 31, 2024, they will not be identified as an OTC monograph drug facility and will not be considered fee liable for purposes of FY 2025 OMUFA facility fees.

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).

I received a fee notice, but I don't think my facility should be charged an OMUFA facility fee for FY 2024. 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 2024 facility fee, please contact CDERCollections@fda.hhs.gov.

What is an FDA Establishment Identifier number?
An FDA Establishment Identifier (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).

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?

Each person that submits an OMOR is subject to an OMOR fee upon submission of the OMOR.

However, a person who submits certain safety-related OMORs will not be subject to an OMOR fee. Specifically, under the statute, no OMOR fee will be assessed if the 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 were OMOR fees calculated?

Under the statute, OMOR fees are adjusted for inflation using the previous fiscal year's OMOR fee rates.