Other OMUFA Fee-Related Questions

Q1. How does a person make payment to satisfy fiscal year (FY) 2021 OMUFA facility fee(s)?

Persons can submit payment to fulfill FY 2021 OMUFA facility fee obligations by:

- Accessing FDA's User Fee System to create an OMUFA Facility Fee Cover Sheet for each assessed facility fee, utilizing the step-by-step instructions;
- Submitting this cover sheet to receive a PIN (i.e., Cover Sheet Number); and
- Completing the FY 2021 OMUFA user fee payment process and making payment via:
    - Electronic check or credit card at FDA's pay.gov website; or
    - Wire transfer from the financial institution of choice, including the unique Cover Sheet Number to ensure that the payment is applied to the correct fee(s).
        - The originating financial institution may charge a wire transfer fee. Applicable wire transfer fees must be included with payment to ensure fees are fully paid.
        - The account information for wire transfers is as follows: U.S. Department of the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Acct. No.: 75060099, Routing No.: 021030004, SWIFT: FRNYUS33. If needed, FDA's tax identification number is 53-0196965.

Q2. What happens if a person does not pay or pays less than the full amount of required OMUFA fee(s)?

FDA's expectation is for full and timely payment of all OMUFA fees by the due date set forth in the annual Federal Register notice. In accordance with section 744M(e) of the Federal Food, Drug, and Cosmetic Act,

- failure to pay the facility fee within 20 calendar days of the due date will result in the Agency placing the facility on a publicly-available arrears list and all over-the-counter (OTC) monograph drug products manufactured at that facility (or containing an ingredient manufactured at that facility) shall be deemed misbranded under section 502(ff) of the FD&C Act. These penalties will apply until the fee obligations are satisfied in full.
- OTC Monograph Order Requests (OMORs) will not be accepted from persons owing fees in arrears (from failure to pay the OMOR or facility fee), and persons owing OMUFA fees will be ineligible for OTC monograph drug meeting requests until all such fees have been paid.

Those paying fees are responsible for determining all financial institution transaction fees that may be deducted from a company's authorized amount for payment to FDA. These include wire transfer and foreign exchange fees. Please ask the financial institution about fees to make sure FDA receives full payment.

Q3. What actions may FDA take if a person refuses to pay my OMUFA fees?

FDA has a range of regulatory/enforcement options for individuals or companies that do not pay the applicable OMUFA fees including issuing warning letters to achieve voluntary compliance, and using various enforcement tools with respect to marketing of products deemed misbranded for failure to pay fees. In any case where payment of the fee is not received within 30 calendar days after it is due, such fee shall be treated as a claim of the United States Government and subject to federal

collection activity. For more information on types of FDA enforcement actions please refer to FDA's website here.

Q4. How does a person request a refund for a fee paid in error?

That person will need to submit a written request justifying return of the erroneous payment within 180 calendar days after the fee was paid. Otherwise, that person will not qualify for the return of a fee claimed to have been paid in error. Persons should provide a written request and a completed Form FDA 3913 to the Division of User Fee Management at CDERCollections@fda.hhs.gov.

Q5. To whom should correspondence be sent regarding user fee issues?

Persons responding to FDA regarding a user fee issue should electronically send a copy of that response to the attention of Division of User Fee Management at CDERCollections@fda.hhs.gov.

This will ensure that the Division of User Fee Management, which is responsible for handling user fee payment questions, is able help resolve any outstanding questions. Given the time-sensitive nature of user fee issues, contacting the Office of Nonprescription Drugs directly, without including the Division of User Fee Management, may result in a delayed response from the FDA.

Q6. Will companies be invoiced for fees?

It is FDA's expectation that a facility meeting the definition of an OTC monograph drug facility that owes fees under section 744M of the Federal Food, Drug, and Cosmetic Act will be registered in FDA's electronic Drug Registration and Listing System (eDRLS) and make appropriate payment through FDA's User Fee System by the payment due date.

FDA will send invoices to those facilities that have not fully satisfied the fee obligation once the payment is past due. In accordance with section 744M(e)(1)(A), FDA places those facilities that have failed to fulfill their OMUFA facility fee(s) obligation within 20 calendars day of the due date on a publicly available arrears list.

Q7. Are there any waivers or exemptions from the fees for categories of drugs?

There are no waivers or exemptions for OMUFA fees.

Q8. What about firms that first registered to make hand sanitizer products during the COVID-19 Public Health Emergency (PHE)?

As noted in the Federal Register notice of March 26, 2021, titled Fee rates under the Over-The-Counter Monograph Drug User Fee Program for Fiscal Year 2021External Link Disclaimer, 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 PHE, solely for purposes of manufacturing hand sanitizer products during the PHE (with the few limitations specified in that Federal Register notice).

Q9. How will FDA communicate and update the arrears list?

The arrears list will be available to the public on FDA's OMUFA website within the User Fee Lists section. FDA plans to update the arrears list following each annual facility fee payment deadline. In addition, FDA anticipates more frequent updates to reflect payment activity.

Q10. If a company believes that its appearance on the arrears list is in error, whom should it contact?

Persons should contact the Over-the-Counter Monograph Drug User Fee Team at CDERCollections@fda.hhs.gov.

Q11. Does OMUFA provide any mechanism for disputes concerning fees?

A person may submit a written request to FDA requesting the return of the fee claimed to be paid in error. The permissible grounds for a refund are discussed in more detail in section 744M of the FD&C Act. Requests justifying the return of a fee claimed to be paid in error must be submitted within 180 calendar days after the fee was paid.

Persons should provide this written request and a completed Form FDA 3913 to the Division of User Fee Management at CDERCollections@fda.hhs.gov.

Q12. What should a person do if a full or partial refund is received and the refund was not expected?

If a person does not know why a refund was received, contact the User Fee Helpdesk at userfees@fda.gov.

- Content current as of:
  06/25/2021
- Regulated Product(s)
  - Drugs
  - Over-the-Counter Drugs