

Prescription Drug User Fee Amendments

Latest News:

- The FY 2026 PDUFA program fee invoices were emailed on August 18, 2025. Full payment of the invoice is due on October 1, 2025. If you do not receive your invoice by August 22, 2025, please contact PDUFA User Fee staff at CDERCollections@fda.hhs.gov (<mailto:CDERCollections@fda.hhs.gov>).
- The FY 2026 PDUFA fee rates were published in the Federal Register (FR) on July 30, 2025. For more information regarding the FY 2026 fee rates, please see the [FR notice available here](https://www.federalregister.gov/public-inspection/2025-14413/prescription-drug-user-fee-rates-for-fiscal-year-2026) (<https://www.federalregister.gov/public-inspection/2025-14413/prescription-drug-user-fee-rates-for-fiscal-year-2026>).
- On September 30, 2022, the President signed into law the FDA User Fee Reauthorization Act of 2022, which includes the reauthorization of the Prescription Drug User Fee Act (PDUFA VII) from fiscal year (FY) 2023 through 2027. Additional information can be found on the [PDUFA VII web page](https://www.fda.gov/industry/prescription-drug-user-fee-amendments/pdufa-vii-fiscal-years-2023-2027) ([/industry/prescription-drug-user-fee-amendments/pdufa-vii-fiscal-years-2023-2027](https://www.fda.gov/industry/prescription-drug-user-fee-amendments/pdufa-vii-fiscal-years-2023-2027)).

FY 2025 and FY 2026 User Fee Rates

Fee Category	Fee Rates for FY 2025	Fee Rates for FY 2026
Application	-	-
Requiring clinical data	\$4,310,002	\$4,682,003
Not requiring clinical data	\$2,155,001	\$2,341,002
Program	\$403,889	\$442,213

Background and Legislation

The Prescription Drug User Fee Act (PDUFA) was created by Congress in 1992 and authorizes FDA to collect user fees from persons that submit certain human drug applications for review or that are named in approved applications as the sponsor of certain

prescription drug products. Since the passage of PDUFA, user fees have played an important role in expediting the drug review and approval process.

PDUFA must be reauthorized every five years, and was renewed in 1997 ([PDUFA II \(/industry/prescription-drug-user-fee-act-pdufa/pdufa-legislation-and-background-pdufa-ii\)](#)), 2002 ([PDUFA III \(/industry/prescription-drug-user-fee-act-pdufa/pdufa-legislation-and-background-pdufa-iii\)](#)), 2007 ([PDUFA IV \(/industry/prescription-drug-user-fee-act-pdufa/pdufa-legislation-and-background-pdufa-iv\)](#)), and 2012 ([PDUFA V \(/industry/prescription-drug-user-fee-act-pdufa/pdufa-v-fiscal-years-2013-2017\)](#)), 2017 ([PDUFA VI \(/industry/prescription-drug-user-fee-act-pdufa/pdufa-vi-fiscal-years-2018-2022\)](#)), and 2022 ([PDUFA VII \(/industry/prescription-drug-user-fee-amendments/pdufa-vii-fiscal-years-2023-2027\)](#)). On September 30, 2022, the President signed into law the FDA User Fee Reauthorization Act of 2022, which includes the reauthorization of PDUFA through September 2027. [PDUFA VII \(/industry/prescription-drug-user-fee-amendments/pdufa-vii-fiscal-years-2023-2027\)](#) will provide for the continued timely review of new drug and biologic license applications.

Federal Register Documents and Guidances

Federal Register Documents

- [Fee Rate for Using a Priority Review Voucher in Fiscal Year 2025 \(/https://www.federalregister.gov/documents/2024/09/19/2024-21433/fee-rate-for-using-a-priority-review-voucher-in-fiscal-year-2025\)](#)
- [Genus Medical Technologies LLC Versus Food and Drug Administration; Request for Information and Comments \(/https://www.federalregister.gov/documents/2021/08/09/2021-16944/genus-medical-technologies-llc-versus-food-and-drug-administration-request-for-information-and\)](#)
- [Establishment of Prescription Drug User Fee Rates for Fiscal Years 1998 – present \(/industry/prescription-drug-user-fee-act-pdufa/pdufa-user-fee-rates-archive\)](#)

Guidances

- [Guidance Documents and MAPPs \(/industry/prescription-drug-user-fee-act-pdufa/guidance-documents-and-mapps-pdufa\)](#)

To find older Federal Register Documents, please visit the [Archive Page \(/industry/prescription-drug-user-fee-act-pdufa/regulations-and-federal-register-documents-pdufa\)](https://www.fda.gov/industry/prescription-drug-user-fee-act-pdufa/regulations-and-federal-register-documents-pdufa).

Application Fees

What is a human drug application?

PDUFA levies a user fee on certain human drug applications. Under PDUFA, the term human drug application means an application for approval of a new drug submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), or licensure of certain biological products under section 351(a) of the Public Health Service Act (PHS Act).

The term human drug application does not include the following:

- A supplement to such an application;
- An application with respect to whole blood or a blood component for transfusion;
- An application with respect to a bovine blood product for topical application licensed before September 1, 1992;
- An application with respect to an allergenic extract product licensed before October 1, 2022;
- An application with respect to a standardized allergenic extract product submitted pursuant to a notification to the applicant from the Secretary regarding the existence of a potency test that measures the allergenic activity of an allergenic extract product licensed by the applicant before October 1, 2022;
- An application with respect to an in vitro diagnostic biologic product licensed under section 351 of the PHS Act;
- An application with respect to a large volume parenteral drug product approved before September 1, 1992;
- An application for a licensure of a biological product for further manufacturing use only;
- An application or supplement submitted by a State or Federal Government entity for a drug that is not distributed commercially.

What are Application Fees?

Each person that submits a human drug application is assessed an application fee as follows:

- A human drug application for which clinical data (other than bioavailability or bioequivalence studies) with respect to safety or effectiveness are required for approval is assessed a full application fee.
- A human drug application for which clinical data with respect to safety or effectiveness are not required for approval is assessed one-half of a full fee.

Human drug application fees are due when the application is submitted.

Are there any exceptions to the fee requirements?

Previously Filed Applications:

- An application fee is not required for the resubmission of an application if the original application of the same product
 - was submitted by a person that paid the fee for the application,
 - was accepted for filing, and
 - was not approved or was withdrawn prior to approval (without a waiver).

Designated Orphan Drug or Indication:

- An application for a prescription drug product that has been designated as a drug for a rare disease or condition under section 526 of the FD&C Act is not subject to an application fee unless the application includes an indication for other than a rare disease or condition.

Skin-Test Diagnostic Products:

- A human drug application for a skin-test diagnostic product shall not be subject to an application fee.
- The term “skin-test diagnostic product” means a product (including positive and negative controls required to interpret the results of such tests):
 - For prick, scratch, intradermal, or subcutaneous administration;
 - Expected to produce a limited, local reaction at the site of administration (if positive), rather than a systemic effect;
 - Not intended to be preventive or therapeutic intervention; and

- Intended to detect an immediate or delayed-type skin hypersensitivity reaction to aid in the diagnosis of:
 - An allergy to an antimicrobial agent;
 - An allergy that is not to an antimicrobial agent, if the diagnostic product was authorized for marketing prior to October 1, 2022; or
 - Infection with fungal or mycobacterial pathogens.

How do I Pay fees?

- Visit our Payment Information and Cover Sheet tab for all the information you will need to pay your application fee.

Prescription Drug Program Fees

What is the definition of a prescription drug product?

Prescription drug product means a specific strength or potency of a drug in final dosage form for which a human drug application has been approved and which may be dispensed only by prescription under section 503(b) of the FD&C Act, and is also on the list of products described in section 505(j)(7)(A), or is on a list created and maintained by the Secretary of products approved under human drug applications under section 351 of the Public Health Service Act.

What are prescription drug program fees?

Prescription drug program fees (program fees) are assessed annually for eligible products. The program fees are assessed for each prescription drug product that is identified in such a human drug application approved as of October 1 of such fiscal year.

In addition, there are instances when a drug product is not considered a prescription drug product because the drug product is in the discontinued section of the Orange Book (<https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm>) or the CBER Billable Biologics List (<https://www.fda.gov/media/113210/download>) or CDER Billable Biologics (<https://www.fda.gov/media/186099/download?attachment>) List as of October 1 of the relevant fiscal year. However, if the drug product becomes a prescription drug product on any subsequent day after October 1 of such fiscal year, the applicant shall pay the annual program fee established for that fiscal year.

Applicants may not be assessed more than five prescription drug program fees for a fiscal year for prescription drug products identified in a single approved application.

Are there drugs that are not included in the term prescription drug product?

Yes. The term prescription drug product does not include the following drugs:

- Whole blood or a blood component for transfusion;
- A bovine blood product for topical application licensed before September 1, 1992;
- An allergenic extract product licensed before October 1, 2022;
- A standardized allergenic extract product submitted pursuant to a notification to the applicant from the Secretary regarding the existence of a potency test that measures the allergenic activity of an allergenic extract product licensed by the applicant before October 1, 2022;
- An in vitro diagnostic biologic product licensed under section 351 of the PHS Act;
- A biological product that is licensed for further manufacturing use only;
- A drug that is not distributed commercially and is the subject of an application or supplement submitted by a State or Federal Government entity.

Are there any exceptions to the fee requirements?

Yes. An annual program fee is not assessed if the prescription drug product is:

- A large volume parenteral product (a sterile aqueous drug product packaged in a single-dose container with a volume greater than or equal to 100 mL, not including powders for reconstitution or pharmacy bulk packages) identified on the list compiled under section 505(j)(7); or
- Pharmaceutically equivalent (as defined in section 314.3 of Title 21, Code of Federal Regulations (or any successor regulation)), to another product on the list of products compiled under section 505(j)(7) (not including the discontinued section of such list); or
- A skin-test diagnostic product. The term “skin-test diagnostic product” means a product (including positive and negative controls required to interpret the results of such tests):
 - For prick, scratch, intradermal, or subcutaneous administration;
 - Expected to produce a limited, local reaction at the site of administration (if positive), rather than a systemic effect;

- Not intended to be a preventive or therapeutic intervention; and
- Intended to detect an immediate or delayed-type skin hypersensitivity reaction to aid in the diagnosis of:
 - An Allergy to an antimicrobial agent;
 - An allergy that is not to an antimicrobial agent, if the diagnostic product was authorized for marketing prior to October 1, 2022; or
 - Infection with fungal or mycobacterial pathogens.

How do I pay a fee?

Visit our Payment Information and Cover Sheet tab for all the information you will need to pay your program fee.

Payment Information and Cover Sheet

When are user fees due?

- An application fee is due when the application is submitted to FDA.
- FDA issues invoices for annual program fees for the coming fiscal year in August of each year using the fee schedule for the coming fiscal year. Payments are due either on the first business day on or after October 1 of each fiscal year or the first business day after the enactment of an appropriations Act providing for the collection and obligation of fees for that fiscal year, whichever occurs later.
- FDA may issue additional invoices as needed. These invoices are also known as clean-up invoices to capture program fees that were not previously invoiced. The clean-up invoices are generally issued in mid-December of the fiscal year and the fees are generally due by mid-January of the fiscal year.

What is the Federal government's fiscal year?

The Federal government's fiscal year begins on October 1 and ends on September 30. For example, fiscal year 2022 begins October 1, 2021, and ends September 30, 2022.

What is the PDUFA User Fee Cover Sheet?

Form FDA 3397, the PDUFA user fee cover sheet, is designed to provide the minimum necessary information to determine whether a fee is required for review of an application, to

determine the amount of the fee required, and to help FDA track payments. The PDUFA Cover Sheet Form FDA 3397 should be completed for the following:

- 505(b) and 351(a) Original Applications
- Resubmission of 505(b) and 351(a) Original Application after a Refuse to File
- Resubmission of 505(b) and 351(a) Original Applications Withdrawn before the filing date.

The form provides a cross-reference of the fee submitted for an application with the actual application by using a unique number tracking system to assign the user fee payment identification number (PIN). The information collected is used by FDA's Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER) to initiate the administrative screening of new drug applications and biologics license applications. Note: You do not need to fill out a Form 3397 for annual program fee payments.

How do I fill out the PDUFA User Fee Cover Sheet Online?

FDA offers you the ability to complete a PDUFA User Fee Cover Sheet online and submit it electronically. Please visit [PDUFA User Fee Coversheet webpage](https://userfees.fda.gov/OA_HTML/pdufaCAcdLogin.jsp) (https://userfees.fda.gov/OA_HTML/pdufaCAcdLogin.jsp) to fill out the form. To fill out the form online, you need Microsoft Internet Explorer 5.5 or higher. For Step-by-Step Instructions on how to fill out the cover sheet, please visit:

https://userfees.fda.gov/OA_HTML/PDUFACSCreation.pdf
(https://userfees.fda.gov/OA_HTML/PDUFACSCreation.pdf).

How do I submit payment after completing the PDUFA User Fee Cover Sheet?

A payment may be submitted electronically via the [User Fees Payment Portal](https://userfees.fda.gov/OA_HTML/fdaExternalBanner.jsp?redirectURL=/OA_HTML/fdaUPPInvSearch.jsp) (https://userfees.fda.gov/OA_HTML/fdaExternalBanner.jsp?redirectURL=/OA_HTML/fdaUPPInvSearch.jsp) or by mailing a check, bank draft, U.S. postal money order, or by wire transfer made payable to the order of the U.S. Food and Drug Administration. For all payment options, the payment must be made in U.S. currency drawn on a U.S. financial institution.

If mailing your payment, please send a printed copy of the completed PDUFA User Fee Cover Sheet along with a check, bank draft, or U.S. Postal money order made payable to the Food and Drug Administration for the fee amount due. Remember to include the user fee payment identification number, beginning with "PD," the BLA/NDA number, and the FDA P.O. Box on the enclosed check.

Mail payment and copy of PDUFA user fee cover sheet to:

Food and Drug Administration
P.O. Box 979107
St. Louis, MO 63197-9000

Note: In no case should payment be submitted with the actual application to CDER/CBER.

If checks are to be sent by a courier that requires a street address, the courier can deliver the checks to:

U.S. Bank
Attn: Government Lockbox 979107
3180 Rider Trail South
Earth City, MO 63045

Note: This address is for courier delivery only.

Wire Transfer Payment

US Department of Treasury
TREAS NYC
33 Liberty Street
New York, NY 10045
FDA Deposit Account Number: 75060099
US Department of Treasury routing/transit number: 021030004
SWIFT Number: FRNYUS33
Beneficiary: FDA
10903 New Hampshire Ave
Bldg. 75, Room #1427
Silver Spring, MD 20903

Note: For wire transfers, please include the user fee payment identification number (PIN), beginning with "PD", the BLA/NDA number and ensure that the fee that your bank will charge for the wire transfer is added to your fee payment.

Please note for payments for annual program fees, it is helpful to include the invoice sheet that was sent to you for the annual program fees (or product or establishment fees).

If you have problems or if you are unsure on whether or not you need to file an application with FDA or are unsure what type of application to file:

Prescription Drug User Fee Staff Contact:

CDERCollections@fda.hhs.gov or 301-796-7900

Center for Biologics Evaluation and Research Contact:

Carla Vincent at 240-402-8177

If you need technical assistance with your cover sheet or are unsure how to proceed:

Contact: FDA User Fee Financial Support Team at (301) 796-7200 or userfees@fda.gov.

PDUFA User Fee Cover Sheet

OMB No. 0910-0297

Form FDA 3397 (03/19)

Waiver, Reductions, Exemptions, and Refunds**Are there any waivers of user fees?**

Under section 736(d) of the FD&C Act, a waiver may be granted for one or more user fees where:

- A waiver or reduction is necessary to protect the public health;
- The assessment of the user fee would present a significant barrier to innovation due to limited resources or other circumstances; or
- The applicant involved is a small business submitting its first human drug application to FDA for review.

To be granted a waiver, the human drug applicant must submit a written request for the waiver. Applicants may submit written requests (for both CDER and CBER products) via email to CDERCollections@fda.hhs.gov (<mailto:CDERCollections@fda.hhs.gov>).

Is there a reduction of fees for human drug applications that are refused for filing or are withdrawn before or after filing?

Yes. The following reductions or refunds are available:

- 75 percent of the application fee is refunded for any application that is refused for filing or is withdrawn before filing.
- If an application 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 application or supplement. FDA

has the sole discretion to refund a fee or a portion of the fee. FDA's determination concerning a refund on this basis is not reviewable.

What is the timeframe for requesting a waiver, reduction, exemption, or refund of fees?

To qualify for consideration, a written request for a waiver, reduction, exemption, or refund must be submitted not later than 180 calendar days after such fee is due (including if the fee is claimed to have been paid in error).

How do I request a small business waiver and refund?

An applicant should submit [Form FDA 3971 \(/media/108984/download?attachment\)](/media/108984/download?attachment) (Small Business Waiver and Refund Request) to CDERCollections@fda.hhs.gov (<mailto:CDERCollections@fda.hhs.gov>) to see if they qualify for a small business waiver.

Who should I contact with questions about how to submit a waiver, reduction, exemption, or refund request?

Please contact CDERCollections@fda.hhs.gov (<mailto:CDERCollections@fda.hhs.gov>) with any questions about submitting your request.

Where should I send my request?

Please submit your request by electronic mail to the Prescription Drug User Fee staff at CDERCollections@fda.hhs.gov (<mailto:CDERCollections@fda.hhs.gov>).

What information should I include in my request?

For more information about submitting a request for a waiver, reduction, exemption, or refund request, please read FDA's guidance for industry [User Fee Waivers, Reductions, and Refunds for Drug and Biological Products \(/media/131797/download\)](/media/131797/download).

Reauthorization Activities

- [PDUFA VIII: Fiscal Years 2028 – 2032 \(/industry/prescription-drug-user-fee-amendments/pdufa-viii-fiscal-years-2028-2032\)](/industry/prescription-drug-user-fee-amendments/pdufa-viii-fiscal-years-2028-2032)
- [PDUFA VII: Fiscal Year 2023 - 2027 \(/industry/prescription-drug-user-fee-amendments/pdufa-vii-fiscal-years-2023-2027\)](/industry/prescription-drug-user-fee-amendments/pdufa-vii-fiscal-years-2023-2027)
- [PDUFA VI Five-Year Financial Plan \(/media/112325/download\)](/media/112325/download) (PDF - 480 KB)

- [PDUFA Meetings \(/industry/prescription-drug-user-fee-act-pdufa/pdufa-meetings\)](/industry/prescription-drug-user-fee-act-pdufa/pdufa-meetings)
- [PDUFA VI Information Technology Goals and Progress \(/industry/prescription-drug-user-fee-act-pdufa/pdufa-vi-information-technology-goals-and-progress\)](/industry/prescription-drug-user-fee-act-pdufa/pdufa-vi-information-technology-goals-and-progress)
- [PDUFA VI: Fiscal Years 2018 - 2022 \(/industry/prescription-drug-user-fee-act-pdufa/pdufa-vi-fiscal-years-2018-2022\)](/industry/prescription-drug-user-fee-act-pdufa/pdufa-vi-fiscal-years-2018-2022)
- Federal Register Notice: [Public Meeting on Proposed Recommendations for PDUFA Reauthorization \(https://www.federalregister.gov/documents/2016/07/19/2016-16916/prescription-drug-user-fee-act-public-meeting-request-for-comments\)](https://www.federalregister.gov/documents/2016/07/19/2016-16916/prescription-drug-user-fee-act-public-meeting-request-for-comments)
- [PDUFA VI Proposed Commitment Letter \(/media/99140/download\)](/media/99140/download)
- [PDUFA V: Fiscal Years 2013-2017 \(/industry/prescription-drug-user-fee-act-pdufa/pdufa-v-fiscal-years-2013-2017\)](/industry/prescription-drug-user-fee-act-pdufa/pdufa-v-fiscal-years-2013-2017)

Related Information

- [FDA Pilot for Original Applications Following STAR Paradigm \(/industry/fda-user-fee-programs/fda-pilot-gain-experience-reviewing-small-number-original-applications-following-split-real-time\)](/industry/fda-user-fee-programs/fda-pilot-gain-experience-reviewing-small-number-original-applications-following-split-real-time)
- [Update on In-Person Face-to-Face Formal Meetings with FDA \(/industry/prescription-drug-user-fee-amendments/update-person-face-face-formal-meetings-fda\)](/industry/prescription-drug-user-fee-amendments/update-person-face-face-formal-meetings-fda)
- [CDER & CBER Net Hiring Data \(/industry/prescription-drug-user-fee-amendments/center-drug-evaluation-and-research-center-biologics-evaluation-and-research-net-hiring-data\)](/industry/prescription-drug-user-fee-amendments/center-drug-evaluation-and-research-center-biologics-evaluation-and-research-net-hiring-data)
- [PDUFA 5 Year Financial Plans \(/about-fda/user-fee-reports/user-fee-five-year-financial-plans\)](/about-fda/user-fee-reports/user-fee-five-year-financial-plans)
- [PDUFA Letters \(/industry/prescription-drug-user-fee-act-pdufa/letters-pdufa\)](/industry/prescription-drug-user-fee-act-pdufa/letters-pdufa)
- [Annual Reports and Plans \(/industry/prescription-drug-user-fee-act-pdufa/pdufa-annual-reports-and-plans\)](/industry/prescription-drug-user-fee-act-pdufa/pdufa-annual-reports-and-plans)
- [Orange Book \(http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm\)](http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm)
- [CDER Therapeutic Biologic Products List \(/media/186099/download?attachment\)](/media/186099/download?attachment) (PDF - 734 KB)
- [CBER Billable Biologics List \(/media/113210/download?attachment\)](/media/113210/download?attachment) (PDF - 953 KB)

- [PDUFA User Fee Rates Archive \(/industry/prescription-drug-user-fee-act-pdufa/pdufa-user-fee-rates-archive\)](/industry/prescription-drug-user-fee-act-pdufa/pdufa-user-fee-rates-archive)
- [Complete Response Letter Final Rule \(/drugs/laws-acts-and-rules/complete-response-letter-final-rule\)](/drugs/laws-acts-and-rules/complete-response-letter-final-rule)
- [PDUFA Financial Reports \(/about-fda/user-fee-financial-reports/pdufa-financial-reports\)](/about-fda/user-fee-financial-reports/pdufa-financial-reports)
- [PDUFA Performance Reports \(/about-fda/user-fee-performance-reports/pdufa-performance-reports\)](/about-fda/user-fee-performance-reports/pdufa-performance-reports)

Contact Us

Questions for the Prescription Drug User Fee staff? Contact us at CDERCollections@fda.hhs.gov (<mailto:CDERCollections@fda.hhs.gov>) or 301-796-7900.

Refund or waiver request? Please email them to CDERCollections@fda.hhs.gov (<mailto: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 (<mailto:userfees@fda.gov>) or call 301-796-7200.

Questions about Pay.gov? Email them at pay.gov.clev@clev.frb.org (<mailto:pay.gov.clev@clev.frb.org>) or call 800-624-1373.

Questions about the Orange Book? Email them at OrangeBook@fda.hhs.gov (<mailto:OrangeBook@fda.hhs.gov>).

In the rare instance where you are unable to submit an electronic request, you may mail your request, via the carrier of your choice, to FDA, Division of User Fee Management, 10001 New Hampshire Ave, Silver Spring, MD 20993.

Was this page helpful? * (required)

Yes

No

Submit

 An official form of the United States government. Provided by [Touchpoints](#)