


MDUFA Premarket Notification 510(k) Cover Sheet Creation: Step-by-Step Instructions

Each person who wants to market in the U.S., a Class I, II, and III device intended for human use, for which a Premarket Approval (PMA) is not required, must submit a 510(k) to FDA unless the device is exempt from 510(k) requirements of the Federal Food, Drug, and Cosmetic Act (the Act) and does not exceed the limitations of exemptions in .9 of the device classification regulation chapters (e.g., 21 CFR 862.9, 21 CFR 864.9). There is no 510(k) form, however, 21 CFR 8071 Subpart E describes requirements for a 510(k) submission. Before marketing a device, each submitter must receive an order, in the form of a letter, from FDA which finds the device to be substantially equivalent (SE) and states that the device can be marketed in the U.S. This order "clears" the device for commercial distribution.

For additional information, please refer to:

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/default.htm>

- 1) Access the User Fee Website: https://userfees.fda.gov/OA_HTML/mdufmaCAcdLogin.jsp
- 2) Review the statement and select the 'I Understand' radio button.
- 3) For users who have an existing user name and password, proceed to Step 4;
 - a. If you do not have an existing account, see the [FDA User Fee Account Creation: Step-by-Step Instructions](#) for step-by-step instructions on how to create an account. For additional assistance, contact the User Fee Helpdesk at userfees@fda.gov.
- 4) Enter a valid user name and password.
- 5) Select the 'Login' button.


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At the end of fiscal year (FY) 2020, FDA will change its policies regarding the transfer of payments across fiscal years to align with the Treasury Accounting Treatment Manual. The Agency will refund payments made to user fee cover sheet ID that are not linked to a submitted application in the previous FY. Applicants with any payment from a prior year without a corresponding application submission should submit a refund request. To request a refund, complete [Form FDA 3913](#) and email the form to userfees@fda.gov. Form FDA 3913 is available at <https://www.fda.gov/downloads/about/fda/budgets/fundamental/forms/UCM419218.pdf>.

Starting in FY 2021, a payment made to a user fee cover sheet within the FY that is not linked to an application submitted in that FY will not be transferred to the new FY. Previous FY payment without an application submission will be refunded and the applicant will have to submit a new user fee cover sheet with a new payment for the new FY.

Payment transfers occurring within the same FY will not be affected by this change in policy. If you have any questions regarding this change, please contact the User Fee Staff at userfees@fda.gov.

Useful Links

- [User Fee Information](#)
- [User Fee Payment Information](#)
- [Frequently Asked Questions \(FAQs\)](#)
- [FDA User Fee Account Creation: Step-by-Step Instructions](#)
- [MDUFA 510\(k\) Cover Sheet Creation: Step-by-Step Instructions](#)
- [MDUFA 513a Cover Sheet Creation: Step-by-Step Instructions](#)
- [MDUFA PMA Cover Sheet Creation: Step-by-Step Instructions](#)
- [MDUFA De Novo Request Cover Sheet Creation: Step-by-Step Instructions](#)

System for Award Management

If you are a domestic entity and are requesting a refund, we recommend that you create an account with the System for Award Management (SAM). SAM validates the registrant information and electronically shares the encrypted data securely with the FDA to facilitate your refund. Click [here](#) to access SAM.

[Privacy Act Notice](#)

Log in to the User Fee System

User Name

Password

[Forgot User Name/Password?](#)

New User? Please register...

User Fee System Alerts

Effective October 1, 2010, FDA implemented new procedures for payment of the MDUFA Annual Fee for Periodic Reporting. As a result, customers are no longer able to create a User Fee Cover Sheet to pay their Annual Fee for Periodic Reporting.

Instead, customers will be sent an Invoice at the end of the quarter in which their PMA periodic report is due. Your invoice will include all the payment submission details required to make your payment.

Further details are provided in the [FAQ](#).

Please note the FDA's user fee credit card limit is \$24,999.99. You will not be able to make an online payment with a credit card for payments over this limit. The ACH online payment option is still available for amounts exceeding the credit card limit.

For customers who need to register their Medical Device Facility, please access the [Electronic Registration & Listing System \(ERLIS\)](#).

Need Help? Click Here For Assistance.

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6) Select the 'Go' button next to 'MDUFA Cover Sheets (PMA, 510k, etc.).'



User Fee Website

Welcome FDA TEST

Annual Establishment Registration

User Fee	Description	
MDUFA Establishment Registration User Fee 2021	FURLS Device Facility User Fee	Go

2021 Cover Sheets

FY 2021 cover sheets should be created for payments associated with submissions to the FDA for the period October 1st, 2020 through September 30th, 2021.

User Fee	Description	
ANIMAL DRUG USER FEE 2021	ADUFA Pre-Market Cover Sheets	Go
ANIMAL GENERIC DRUG USER FEE 2021	AGDUFA Cover Sheets	Go
Biosimilar User Fee 2021	BsUFA Cover Sheets	Go
Generic Drug User Fee 2021	GDUFA Cover Sheets	Go
Medical Device User Fee 2021	MDUFA Cover Sheets (PMA, 510k, etc.)	Go
Prescription Drug User Fee 2021	PDUFA Pre-Market Cover Sheets	Go

***To view the 2021 fees, please see the Federal Register Notices below:**

[ADUFA 2021 FR Notice](#)
[AGDUFA 2021 FR Notice](#)
[BsUFA 2021 FR Notice](#)
[GDUFA 2021 FR Notice](#)
[MDUFA 2021 FR Notice](#)
[MCM PRV 2021 FR Notice](#)
[PDUFA 2021 FR Notice](#)
[PRV 2021 FR Notice](#)
[RPD PRV 2021 FR Notice](#)

***To view the 2020 fees, please see the Federal Register Notices below:**

[GDUFA 2020 FR Notice](#)

7) Select 'Continue' button at the bottom of the page.

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Medical Device User Fee

User Fee Websites

[Food and Drug Administration](#)
[Center for Biologics Evaluation and Research](#)
[Center for Devices and Radiological Health](#)

Please review the important message below regarding a change in policy on payment transfers across FYs before proceeding to the next step.

At the end of fiscal year (FY) 2020, FDA will change its policies regarding the transfer of payments across fiscal years to align with the Treasury Accounting Treatment Manual. The Agency will refund payments made to user fee cover sheet ID that are not linked to a submitted application in the previous FY. Applicants with any payment from a prior year without a corresponding application submission should submit a refund request. To request a refund, complete [Form FDA 3913](#) and email the form to userfees@fda.gov. Form FDA 3913 is available at <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM492188.pdf>.

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Payment transfers occurring within the same FY will not be affected by this change in policy. If you have any questions regarding this change, please contact the User Fee Staff at userfees@fda.gov.

Click "Continue" if you still want to proceed with creating your cover sheet or click "Go Back" to choose the correct FY's cover sheet.

[Go Back](#) [Continue](#)

[User Fees](#) | [Draft Cover Sheet](#) | [Previous Cover Sheet](#) | [Profile](#) | [Logout](#)

FDA Home Page | Search FDA Site | Contact FDA | Privacy | Accessibility
 FDA Website Management Staff

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- 8) Select 'Yes' or 'No' to if your company has paid all establishment registrations fees that are due to the FDA.

The screenshot shows the FDA Medical Device User Fee website. At the top is the FDA logo and navigation links: FAQ, User Fees, Draft Cover Sheet, Previous Cover Sheet, Profile, and Logout. A red banner at the top right reads "Medical Device User Fee". Below this, a red box contains the text: "FDA will not accept your submission if your company has not paid an establishment registration fee that is due to FDA. Has your company paid all establishment registration fees that are due to FDA?". Below this, there are two radio buttons: "YES (All of your establishments have registered and paid the fee, or this is your first device and you will register and pay the fee within 30 days after entering into an operation that requires you to register and submit device listing information.)" and "NO (If you currently market a medical device and your establishment is required to register and submit device listing information, FDA will not accept your submission until you have paid all fees due to FDA. See [Who Must Register, List and Pay the Fee](#) for additional information.)". The "YES" radio button is selected. Below the radio buttons is a table with two columns: "Medical Device User Fee Cover Sheet" and "Application Details". At the bottom of the page, there is a footer with links: FDA Home Page | Search FDA Site | Contact FDA | Privacy | Accessibility | FDA Website Management Staff.

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9) Select the 'Application Details' button.

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[Medical Device User Fee](#)

User Fee Websites

[Food and Drug Administration](#)
[Center for Biologics Evaluation and Research](#)
[Center for Devices and Radiological Health](#)

FDA will not accept your submission if your company has not paid an establishment registration fee that is due to FDA. Has your company paid all establishment registration fees that are due to FDA?

☒ YES (All of your establishments have registered and paid the fee, or this is your first device and you will register and pay the fee within 30 days after entering into an operation that requires you to register and submit device listing information.)
☐ NO (If you currently market a medical device and your establishment is required to register and submit device listing information, FDA will not accept your submission until you have paid all fees due to FDA. See [Who Must Register, List and Pay the Fee](#) for additional information.)

Medical Device User Fee Cover Sheet [Application Details](#)

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MDUFA Premarket Notification 510(k) Cover Sheet Creation: Step-by-Step Instructions

10) Make the appropriate selections to configure your cover sheet and select 'Continue' to proceed.

- Select 'Center for Devices and Radiological Health (CDRH)' or 'Center for Biologics Evaluation and Research (CBER)'
- Select 'Premarket notifications (510(k)); except for third party' for your type of premarket application

Information

- Please select the appropriate center
- Please select the application type

MDUFA COVER SHEET

PLEASE SELECT THE APPROPRIATE CENTER

If you are unsure about which center to choose, please scroll over the options for more information or contact the User Fee Helpdesk at userfee@fda.gov or (301) 796-7200

☒ Center for Devices and Radiological Health (CDRH)
 FDA's Center for Devices and Radiological Health (CDRH) is responsible for regulating firms who manufacture, repack, relabel, and/or import medical devices sold in the United States.

☐ Center for Biologics Evaluation and Research (CBER)
 CBER is the Center within FDA that regulates biological products for human use under applicable federal laws, including the Public Health Service Act and the Federal Food, Drug and Cosmetic Act.

TYPE OF PREMARKET APPLICATION

Select an application type:

☒ Premarket notification (510(k)), except for third party

☐ Biologics License Application (BLA)

☐ Premarket Approval Application (PMA)

☐ Product Development Protocol (PDP)

☐ Premarket Report (PMR)

☐ Modular PMA

☐ 30 Day Notice

☐ 510(k) Request For Information

☐ No Notice Request

Cancel Continue

11) Once you have verified your selection of the MDUFA Cover Sheet page, select 'Continue' to proceed.

*****Please note that this example is for 'Center for Devices and Radiological Health (CDRH)' and 'Premarket notification (510(k)); except for third party'.**

12) Select the appropriate response to indicate whether you are a small business. If you select 'Yes', enter a valid Small Business Decision number. Otherwise select the 'No' option.

On the Small Business Waiver page, select 'Yes' or 'No' if you are a small business.

- Click [here](#) for more information on qualifying as a Small Business with the FDA, or contact Division of Small Manufacturers, International and Consumer Assistance (DSMICA) at dsmica@fda.hhs.gov or (301) 796-7100.
- If 'No' is selected, click 'Continue' to proceed.

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Small Business Waiver

Cancel Back Continue

Please select if you are a small business

☒ Yes ☐ No

If you have selected "Yes" that you are a small business, you have to enter a valid SBD number for the current FDA fiscal year.

Small Business Decision #

If you believe you are a Small Business and would like to qualify for reduced fees, submit a Small Business Qualification Certification. The Small Business Qualification Certification can be found [HERE](#).

If you qualify, you will receive a Small Business Decision (SBD) number. You must provide your SBD number in the Medical Device User Fee Cover Sheet at the time of submission to be eligible for reduced fees. FDA will not accept reduced fees without a SBD number and will not refund the difference between the standard fee and the small business fee after the submission has been received.

Cancel Back Continue

13) If none of the exemptions are applicable, click 'Continue' to proceed without making a selection.

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Medical Device User Fee

Exemptions

Cancel Back Continue

Please check one of the following exemptions if they apply.

☒ This application is submitted by a state or federal government entity for a device that is not to be distributed commercially.

☐ The sole purpose of the application is to support conditions of use for a pediatric population.

Cancel Back Continue

14) Select 'Proceed' to review your cover sheet and submit it to the FDA.

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Medical Device User Fee

Submission

Cancel Back Continue

Please click the "Proceed" button to review your cover sheet and submit it to FDA.

Cancel Back Continue

MDUFA Premarket Notification 510(k) Cover Sheet Creation: Step-by-Step Instructions

15) After arriving at the 'Draft Cover Sheet' page, verify the amount and select the 'Next' button to proceed.

- a. **Note:** you may save the cover sheet by selecting the 'Save Cover Sheet' button. You may return to the 'Draft Cover Sheet' menu to access your saved draft cover sheet. Select the checkbox under the 'Delete' column and select the 'Delete Selected Draft(s)' button to delete a draft cover sheet.

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Medical Device User Fee

Cover Sheet Saved Cover Sheets

Draft Cover Sheet

Items

✓ You now have four options to proceed:

1. If you have one draft cover sheet, click the "Next" button to submit your cover sheet to FDA and receive a Payment Identification Number (PIN).
Note: If you do not receive a Payment Identification Number (PIN), your cover sheet was not submitted to FDA.
2. If you would like to modify your cover sheet selections, click the "Modify Application Details" button to make changes to the draft form. To view your draft cover sheet, please click on the cover sheet link.
3. If you choose not to save or submit your cover sheet at this time, your draft cover sheet will be automatically saved for 30 days before it expires.
4. If you would like to save your cover sheet for future submission, click the "Save Cover Sheet" button and provide a name for your cart.
 If you are saving more than one cover sheets, please make sure you save each cover sheet under a different cart name.
Note: To modify or submit a saved cover sheet, click the "Draft Cover Sheet" icon, and select the "Saved Cover Sheets" link to access your carts. Saved cover sheets remain active for 90 days before they expire.

Select All		Clear Selections				
Delete	Cover Sheet	Creation Date	Last Update Date			
<input type="checkbox"/>	Medical Device User Fee Cover Sheet Modify Application Details	04-JAN-2021 14:27:39	04-JAN-2021 14:41:44			Net: \$12,432.00

[User Fees](#) | [Draft Cover Sheet](#) | [Previous Cover Sheet](#) | [Profile](#) | [Logout](#) |

[Delete Selected Draft\(s\)](#) | [Save Cover Sheet](#) | [Next](#)

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- 16) On the 'Checkout: Applicant Contact Information' page, you will see the billing information for this cover sheet. You can change the address by selecting the 'Change' button and follow the instructions to update the address. Once the information has been verified and is accurate, select 'Next' to proceed.

The screenshot shows the FDA's MDUFA Premarket Notification 510(k) Cover Sheet Creation interface. At the top is the FDA logo and the text "U.S. Food and Drug Administration Protecting and Promoting Your Health". Below this is a navigation bar with icons for FAQ, User Fees, Draft Cover Sheet, Previous Cover Sheet, Profile, and Logout. The main heading is "Checkout: Applicant Contact Information". Below this is a section titled "Payment Information". The "Bill To" section is highlighted with a red box and contains the following information: Customer: PHARMGATE INC, Contact: FDA TEST, 123-1231234, userfees@fda.gov, Address: 1015 ASHES DR, STE 102, WILMINGTON, NC 28405, UNITED STATES. To the right of this section is a "Change" button, also highlighted with a red box. At the bottom right, there are "Save Cover Sheet" and "Next" buttons, with the "Next" button highlighted with a red box. At the bottom of the page, there is a navigation bar with links for User Fees, Draft Cover Sheet, Previous Cover Sheet, Profile, and Logout.

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Checkout: Applicant Contact Information

Payment Information

Bill To

Customer: PHARMGATE INC

Contact: FDA TEST
123-1231234
userfees@fda.gov

Address: 1015 ASHES DR
STE 102
WILMINGTON, NC 28405
UNITED STATES

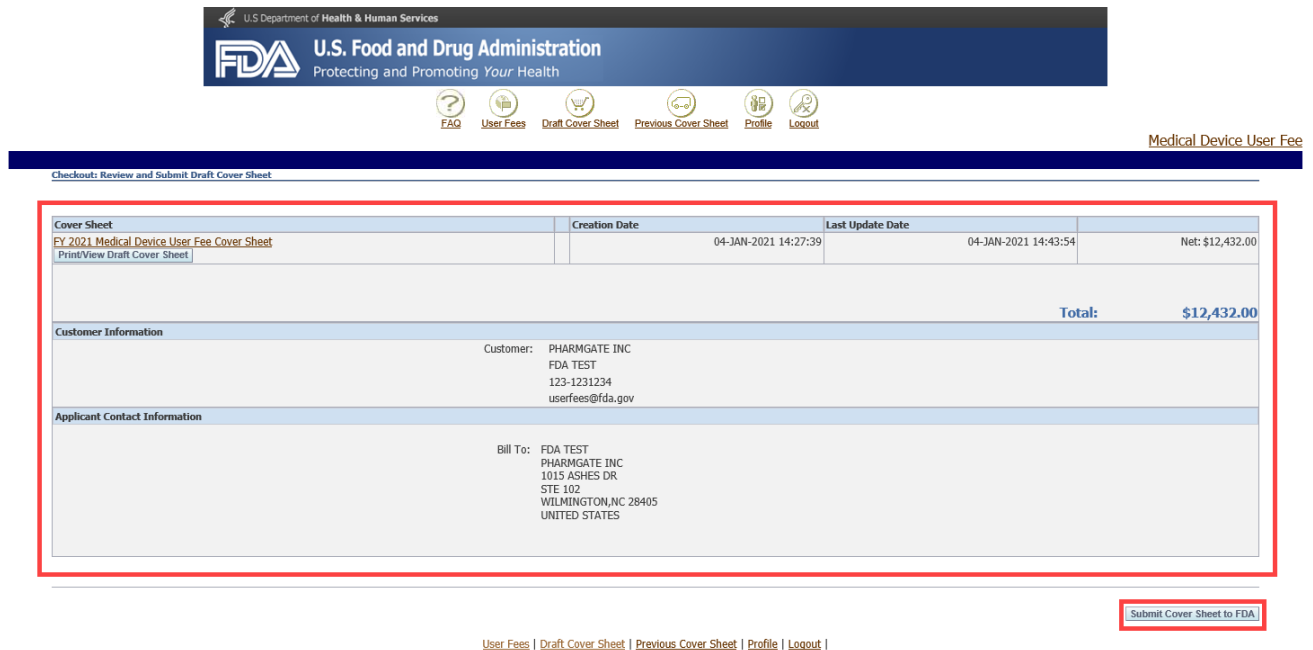
Change

Save Cover Sheet Next

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- 17) Review and verify your information, and select the 'Submit Cover Sheet to FDA' button to obtain your Payment Identification Number (PIN).



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Medical Device User Fee

Checkout: Review and Submit Draft Cover Sheet

Cover Sheet	Creation Date	Last Update Date	
FY 2021 Medical Device User Fee Cover Sheet Print/View Draft Cover Sheet	04-JAN-2021 14:27:39	04-JAN-2021 14:43:54	Net: \$12,432.00

Total: \$12,432.00

Customer Information

Customer: PHARMGATE INC
 FDA TEST
 123-1231234
 userfees@fda.gov

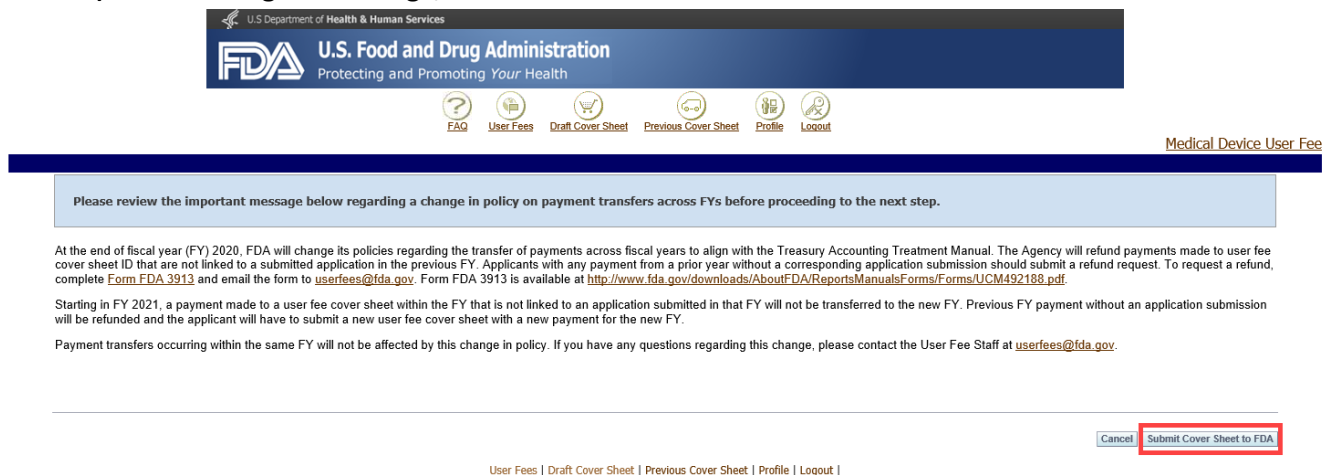
Applicant Contact Information

Bill To: FDA TEST
 PHARMGATE INC
 1015 ASHES DR
 STE 102
 WILMINGTON, NC 28405
 UNITED STATES

[Submit Cover Sheet to FDA](#)

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- 18) After reading the message, select 'Submit Cover Sheet to FDA'.



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[Cancel](#) [Submit Cover Sheet to FDA](#)


[User Fees](#) | [Draft Cover Sheet](#) | [Previous Cover Sheet](#) | [Profile](#) | [Logout](#)

- 19) A unique User Fee PIN will be generated with your cover sheet upon submission. Please note that your completed cover sheet is your invoice. To obtain an invoice copy for your records, select on the 'Print/View Final Cover Sheet' button on the 'Confirmation' page.

Once you submit your cover sheet and obtain your PIN, you may pay online by selecting the 'Pay Now' button.

You can create and submit another MDUFA cover sheet by selecting the 'Create Another Cover Sheet' button.

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Medical Device User Fee

Confirmation
 YOUR PAYMENT IDENTIFICATION NUMBER IS **MD6119727**

Your Cover Sheet has been submitted electronically. You must print and sign the hard copies. Include one in each copy of your application and include a copy with your payment.

Thank you for visiting the FDA User Fee Website. As part of our efforts to improve customer service, we would like to hear from you.

Please [click here](#) to fill out a short survey. This will only take approximately 2 minutes to complete.

Cover Sheet	Creation Date	Last Update Date	
FY 2021 Medical Device User Fee Cover Sheet Print/View Final Cover Sheet	1	04-JAN-2021 14:27:39	04-JAN-2021 14:43:54 Net: \$12,432.00
			Total: \$12,432.00

Customer Information

Customer: PHARMGATE INC
 FDA TEST
 123-1231234
 userfees@fda.gov

Applicant Contact Information

Bill To: FDA TEST
 PHARMGATE INC
 1015 ASHES DR
 STE 102
 WILMINGTON, NC 28405
 UNITED STATES

[Pay Now](#)
[Create Another Cover Sheet](#)

[User Fees](#) | [Draft Cover Sheet](#) | [Previous Cover Sheet](#) | [Profile](#) | [Logout](#)

Note: You can submit payment online by credit card or Automated Clearing House (ACH) electronic check (eCheck), by paper check or by wire/bank transfer. There is a credit card payment limit of \$24,999.99. Any payment above the limit will need to be paid using another payment method. The preferred payment method is online. If you prefer to pay via check or wire transfer, please write the PIN on the check or include the PIN with your wire transfer payment. FDA will not be able to process your payment correctly without your PIN.

If you have any further questions about the cover sheet creation process, please contact the User Fee Helpdesk at userfees@fda.gov.



Last Updated: January 4,

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公众号
专业医疗器械资讯平台
WECHAT OF
HLONGMED

hlongmed.com
医疗器械咨询服务
MEDICAL DEVICE
CONSULTING
SERVICES

医课培训平台
医疗器械任职培训
WEB TRAINING
CENTER

医械宝
医疗器械知识平台
KNOWLEDG
ECENTEROF
MEDICAL DEVICE

MDCPP.COM
医械云专业平台
KNOWLEDG
ECENTEROF MEDICAL
DEVICE