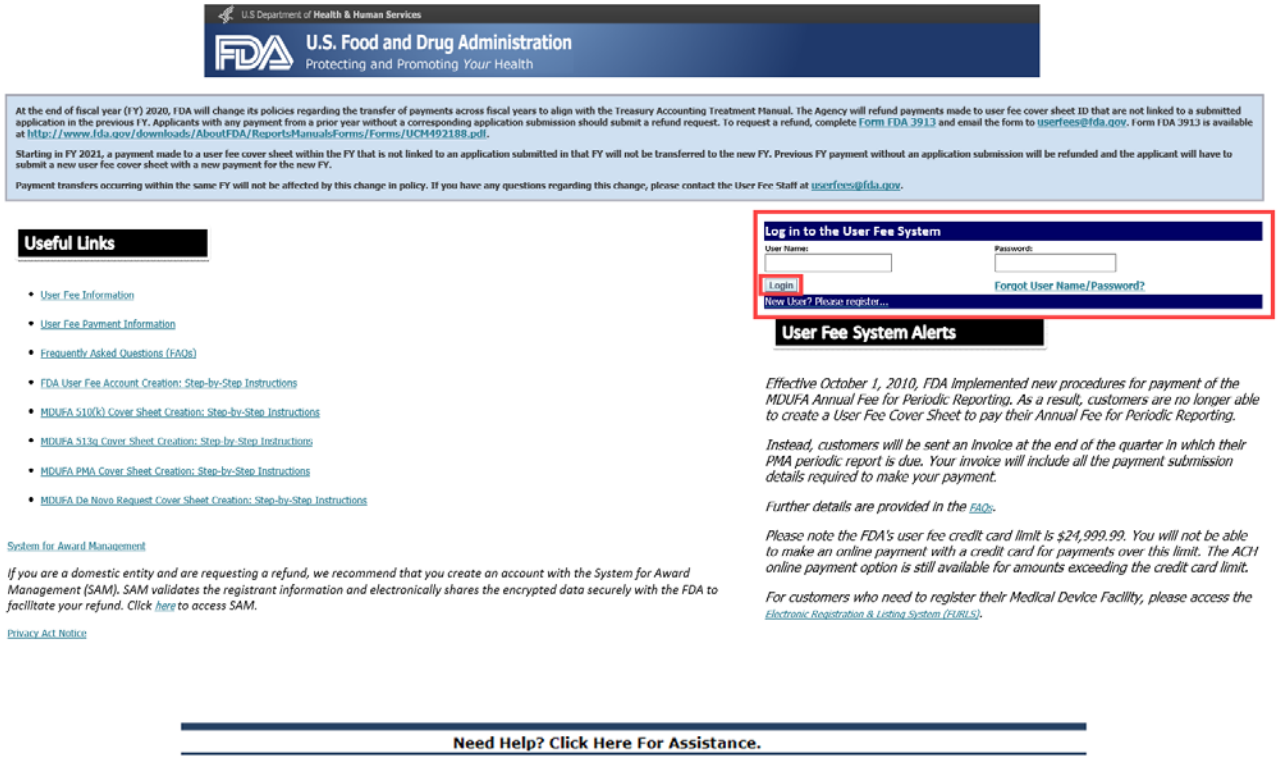
MDUFA Premarket Notification 510(k) Cover Sheet Creation: Step-by-Step Instructions

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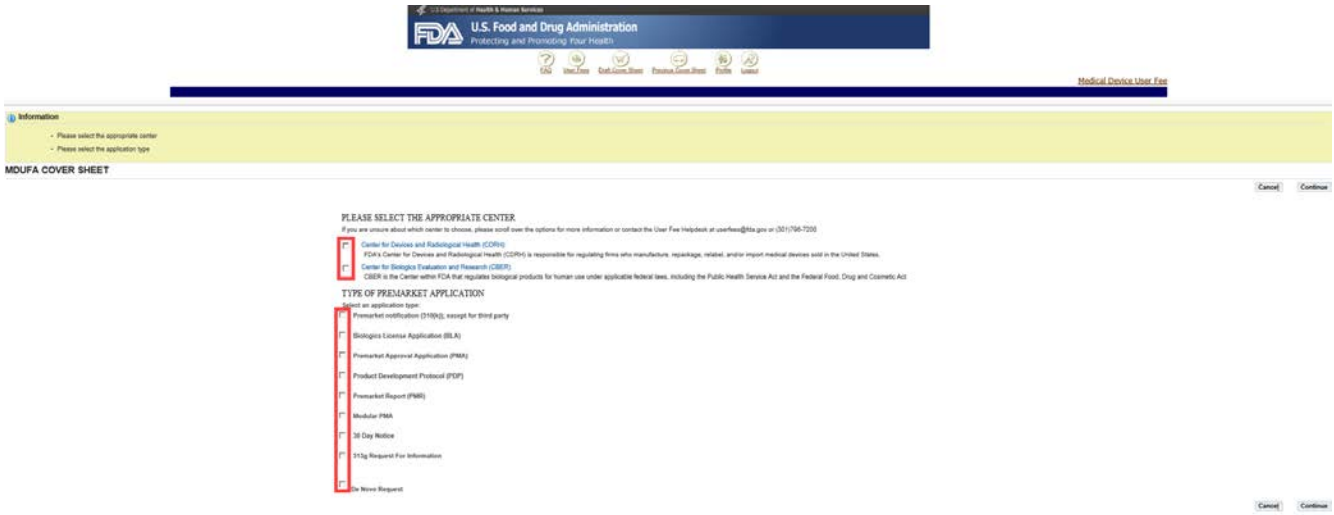
8) Select 'Yes' or 'No' to if your company has paid all establishment registrations fees that are due to the FDA.

9) Select the 'Application Details' button.

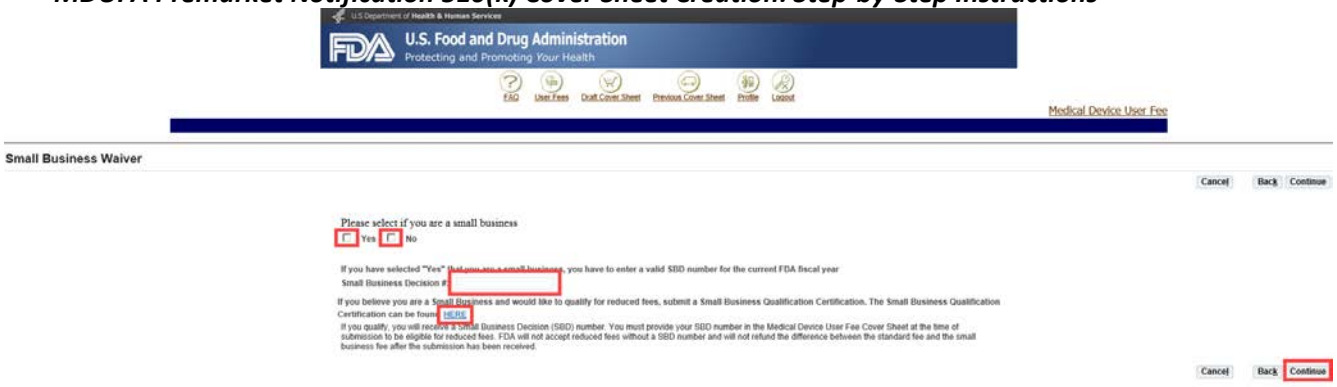
10) **Make the appropriate selections to configure your cover sheet and select 'Continue' to proceed.**
    a. **Select 'Center for Devices and Radiological Health (CDRH)' or 'Center for Biologics Evaluation and Research (CBER)'**
    b. **Select 'Premarket notifications (510(k)); except for third party' for your type of premarket application**



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

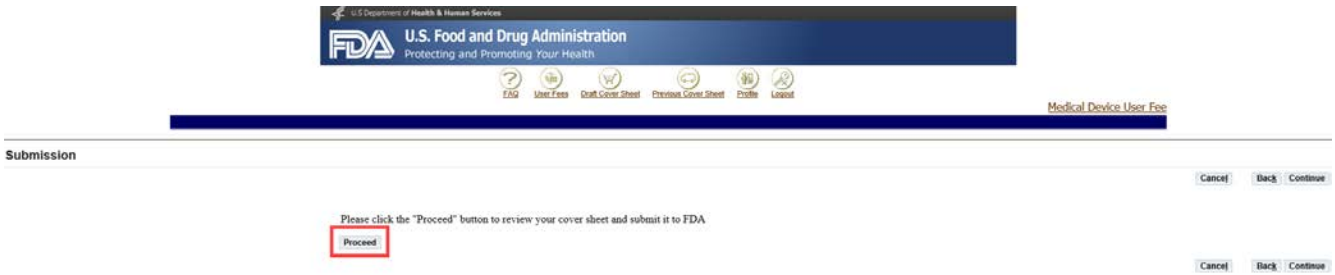
******Please note that this example is for 'Center for Devices and Radiological Health (CDRH)' and 'Premarket notification (510(k)); except for third party'.***

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.
    a. **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.**
    b. **If 'No' is selected, click 'Continue' to proceed.**



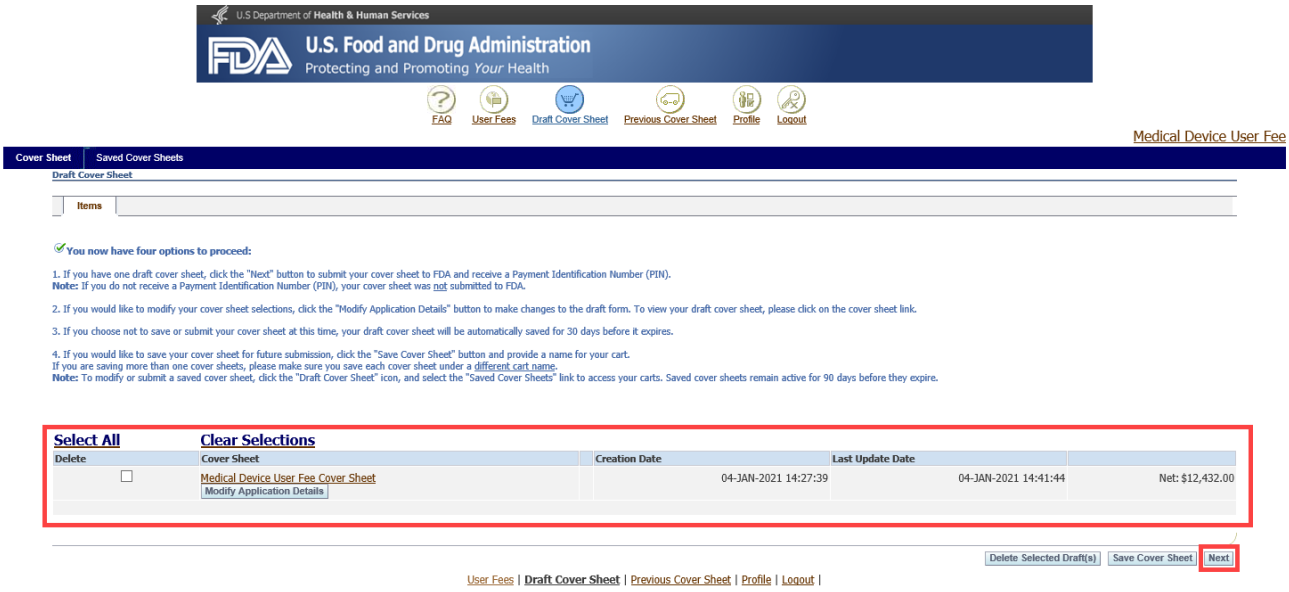
13) If none of the exemptions are applicable, click 'Continue' to proceed without making a selection.

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

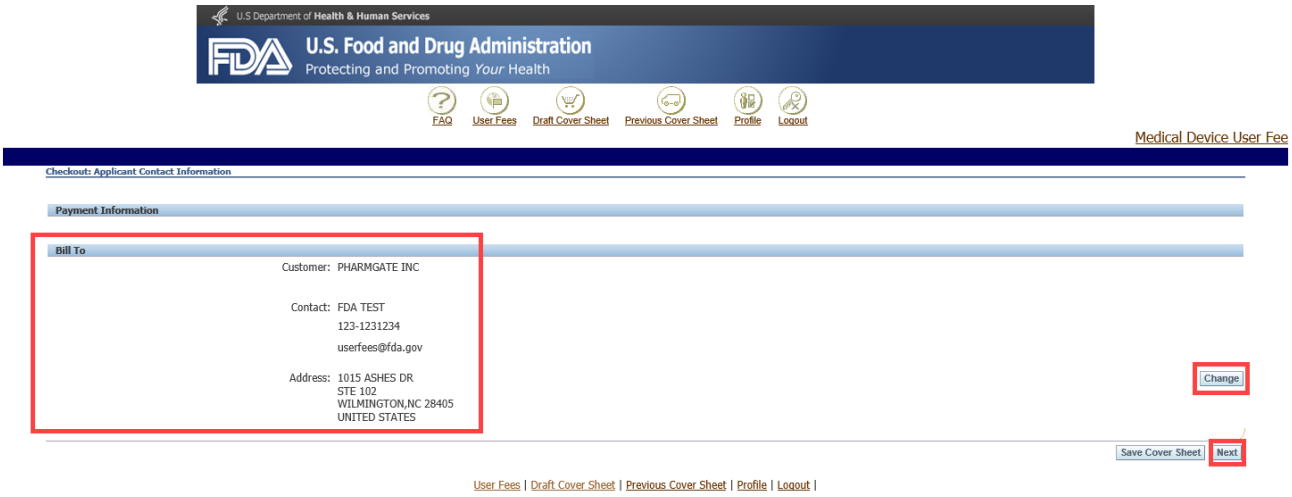


15) After arriving at the 'Draft Cover Sheet' page, verify the amount and select the 'Next' button to proceed.

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.



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.



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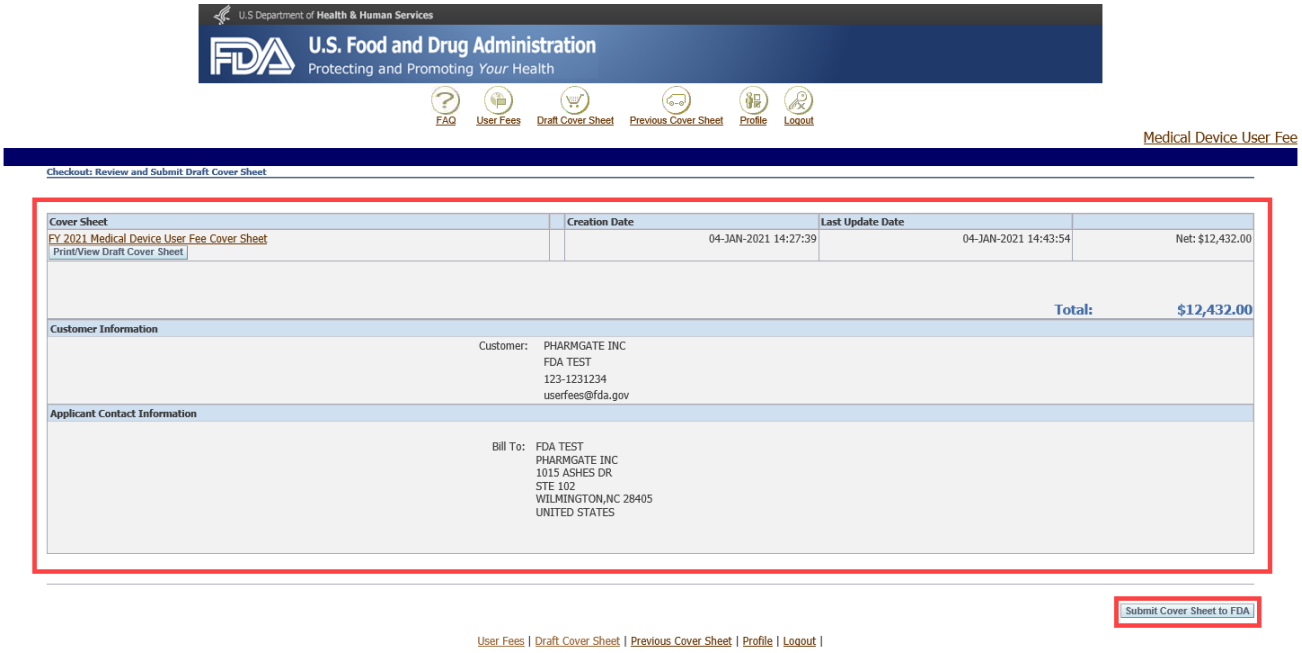
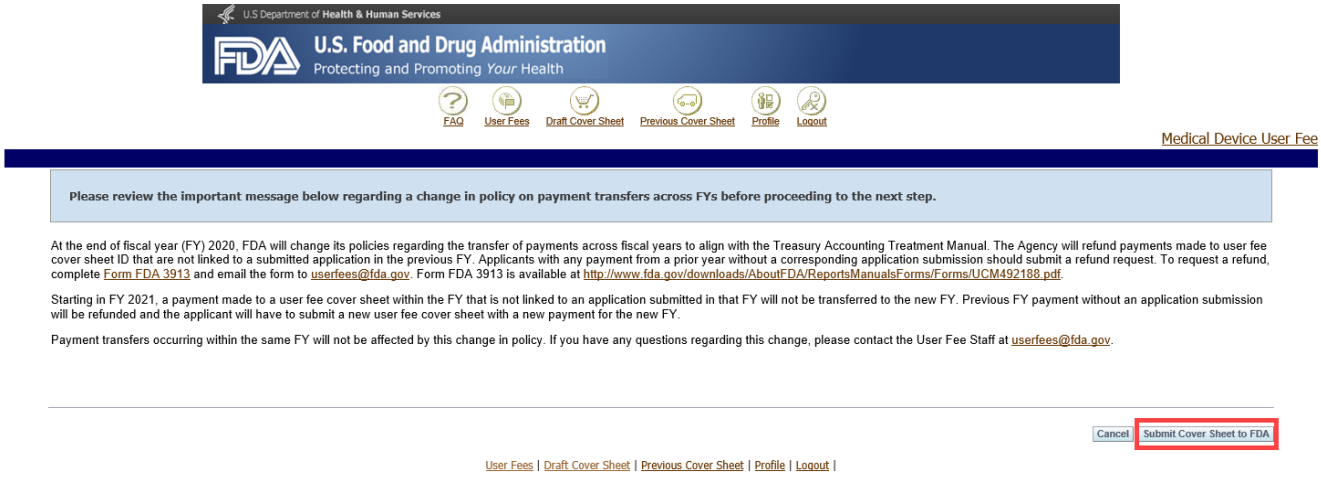
17) Review and verify your information, and select the 'Submit Cover Sheet to FDA' button to obtain your Payment Identification Number (PIN).



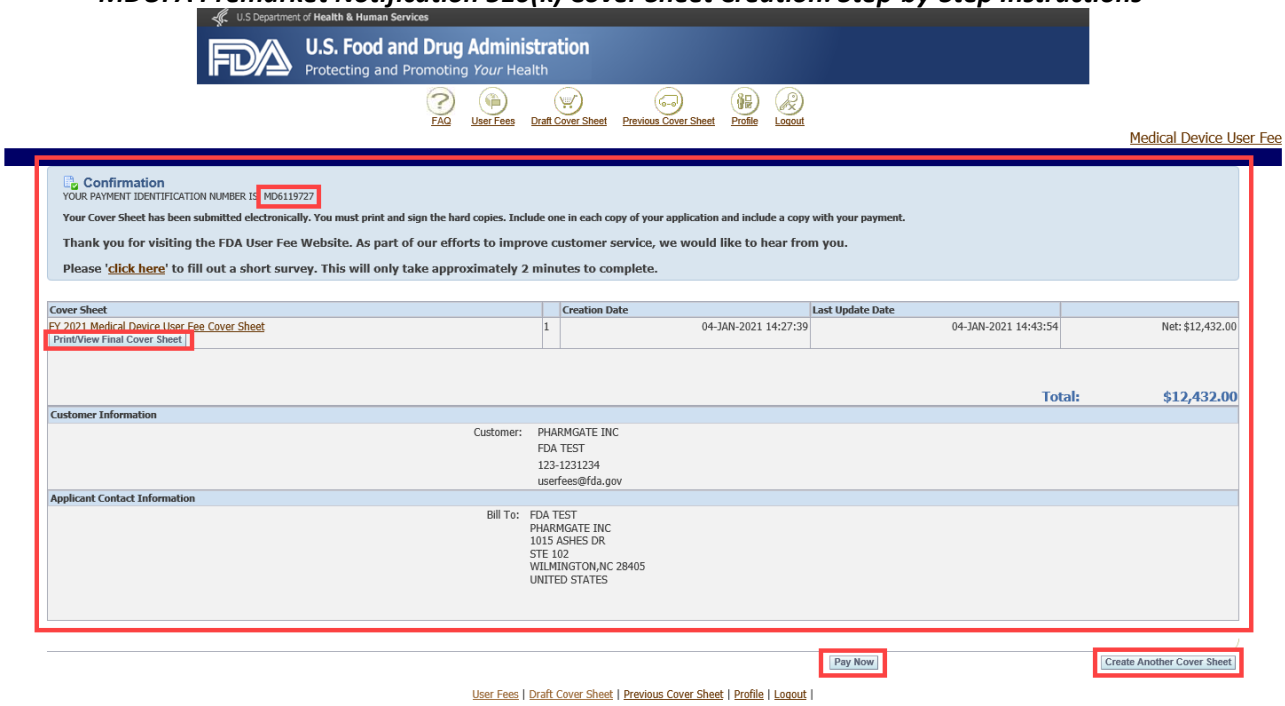
18) After reading the message, select 'Submit Cover Sheet to FDA'.



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.



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.