

## MDUFA 513g Request for Information Cover Sheet Creation: Step-by-Step Instructions

Within 60 days of the receipt of a written request of any person for information respecting the class in which a device has been classified or the requirements applicable to a device under this Act, the Secretary shall provide such person a written statement of the classification (if any) of such device and the requirements of this Act applicable to the device.

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](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](mailto:userfees@fda.gov).
- 4) Enter a valid user name and password.
- 5) Select the 'Login' button.



### Useful Links

- [User Fee Information](#)
- [User Fee Payment Information](#)
- [Frequently Asked Questions \(FAQs\)](#)
- [FDA User Fee Account Creation Process User Guide](#)

#### Central Contractor Registry (CCR)

In the event that you are entitled to a refund, your registration with CCR validates the registrant information and electronically shares the encrypted data securely with the FDA to facilitate your refund. Click [here](#) to access CCR

#### 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 [FAQs](#).

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

**Need Help? Click Here For Assistance.**

## MDUFA 513g Request for Information Cover Sheet Creation: Step-by-Step Instructions

- 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 2014	FURLS Device Facility User Fee	<input type="button" value="Go"/>

#### Cover Sheets

User Fee	Description	
Animal Drug User Fee 2014*	ADUFA Pre-Market Cover Sheets	<input type="button" value="Go"/>
Animal Generic Drug User Fee 2014*	AGDUFA Cover Sheets	<input type="button" value="Go"/>
Biosimilar User Fee 2014*	BsUFA Cover Sheets	<input type="button" value="Go"/>
Generic Drug Backlog Fee*	GDUFA Backlog Fee Cover Sheets	<input type="button" value="Go"/>
Generic Drug User Fee 2013*	GDUFA Cover Sheets	<input type="button" value="Go"/>
Generic Drug User Fee 2014*	GDUFA Cover Sheets	<input type="button" value="Go"/>
Medical Device User Fee 2014*	MDUFA Cover Sheets (PMA, 510k, etc.)	<input type="button" value="Go"/>
Prescription Drug User Fee 2014*	PDUFA Pre-Market Cover Sheets	<input type="button" value="Go"/>

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

U.S. Department of Health & Human Services  
**FDA** U.S. Food and Drug Administration  
 Protecting and Promoting Your Health

FAQ User Fees Draft Cover Sheet Previous Cover Sheet Profile Logout

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

## MDUFA 513g Request for Information Cover Sheet Creation: Step-by-Step Instructions

8) Select the 'Application Details' button.

The screenshot shows the FDA Medical Device User Fee portal. At the top, there is a navigation bar with the FDA logo and the text "U.S. Food and Drug Administration Protecting and Promoting Your Health". Below this, there are several icons for navigation: FAQ, User Fees, Draft Cover Sheet, Previous Cover Sheet, Profile, and Logout. On the right side of the navigation bar, the text "Medical Device User Fee" is visible. Below the navigation bar, there is a section titled "User Fee Websites" with links to "Food and Drug Administration", "Center for Biologics Evaluation and Research", and "Center for Devices and Radiological Health". The main content area contains a question: "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?". There are two radio button options: "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.)". Below this, there is a table with two buttons: "Medical Device User Fee Cover Sheet" and "Application Details". The "Application Details" button is highlighted with a red border.

## MDUFA 513g Request for Information Cover Sheet Creation: Step-by-Step Instructions

- 9) 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 '513g Request For Information' for your type of premarket application.

U.S. Department of Health & Human Services  
**FDA** U.S. Food and Drug Administration  
 Protecting and Promoting Your Health

FAQ User Fees Draft Cover Sheet Previous Cover Sheets Profile Logout

Medical Device User Fee

**Information**

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

**MDUFA COVER SHEET** Cancel Continue

**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 [userfees@fda.gov](mailto:userfees@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

513g Request For Information

Cancel Continue

## MDUFA 513g Request for Information Cover Sheet Creation: Step-by-Step Instructions

10) 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 '513g Request For Information'.**

U.S. Department of Health & Human Services  
**FDA** U.S. Food and Drug Administration  
 Protecting and Promoting Your Health

FAQ User Fees Draft Cover Sheet Previous Cover Sheets Profile Logout

Medical Device User Fee

MDUFA COVER SHEET

Cancel Back Continue

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 [userfees@fda.gov](mailto:userfees@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, repackage, relabel, and/or import medical devices sold in the United States.

TYPE OF PREMARKET APPLICATION  
 Select an application type:  
 513g Request For Information

Cancel Back Continue

11) 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](mailto:dsmica@fda.hhs.gov) or (301) 796-7100.
- If 'No' is selected, click 'Continue' to proceed.

U.S. Department of Health & Human Services  
**FDA** U.S. Food and Drug Administration  
 Protecting and Promoting Your Health

FAQ User Fees Draft Cover Sheet Previous Cover Sheets Profile Logout

Medical Device User Fee

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

**MDUFA 513g Request for Information Cover Sheet Creation: Step-by-Step Instructions**

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

The screenshot shows the FDA Medical Device User Fee interface. At the top, there is a navigation bar with the FDA logo and the text "U.S. Food and Drug Administration Protecting and Promoting Your Health". Below this is a menu with icons for "FAQ", "User Fees", "Draft Cover Sheet", "Previous Cover Sheets", "Profile", and "Logout". A "Medical Device User Fee" button is visible in the top right corner. The main content area is titled "Exemptions" and contains the following text: "Please check one of the following exemptions if they apply." Below this are two radio button options:   
1.  This application is submitted by a state or federal government entity for a device that is not to be distributed commercially   
2.  The sole purpose of the application is to support conditions of use for a pediatric population   
At the bottom right of the form, there are three buttons: "Cancel", "Back", and "Continue". The "Continue" button is highlighted with a red border.

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

The screenshot shows the FDA Medical Device User Fee interface. At the top, there is a navigation bar with the FDA logo and the text "U.S. Food and Drug Administration Protecting and Promoting Your Health". Below this is a menu with icons for "FAQ", "User Fees", "Draft Cover Sheet", "Previous Cover Sheets", "Profile", and "Logout". A "Medical Device User Fee" button is visible in the top right corner. The main content area is titled "Submission" and contains the following text: "Please click the 'Proceed' button to review your cover sheet and submit it to FDA". Below this text is a single button labeled "Proceed", which is highlighted with a red border. At the bottom right of the form, there are three buttons: "Cancel", "Back", and "Continue".

## MDUFA 513g Request for Information Cover Sheet Creation: Step-by-Step Instructions

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

Medical Device User Fee



**U.S. Food and Drug Administration**  
Protecting and Promoting Your Health

U.S. Department of Health & Human Services

FAQ User Fees **Draft Cover Sheet** Previous Cover Sheets Profile Logout

---

Cover Sheet Saved Cover Sheets

Draft Cover Sheet

---

**Items**

You now have four options to proceed:

- 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.
- 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.
- 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.
- 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"/>	<a href="#">Medical Device User Fee Cover Sheet</a> <span style="border: 1px solid #ccc; border-radius: 5px; padding: 2px;">Modify Application Details</span>	13-JAN-2014 17:19:06	13-JAN-2014 17:23:20	Net: \$3,490.00

Delete Selected Draft(s)   Save Cover Sheet   Next

**MDUFA 513g Request for Information Cover Sheet Creation: Step-by-Step Instructions**

- 15) 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.



Checkout: Applicant Contact Information

**Payment Information**

**Bill To**

Customer: FDA TEST COMPANY

Contact: FDA TEST  
123-4567889  
userfees@fda.gov

Address: 123 Medical Drive  
Rockville,  
USA  
MD 20850  
UNITED STATES

Change

Save Cover Sheet

Next

## MDUFA 513g Request for Information Cover Sheet Creation: Step-by-Step Instructions

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

U.S. Department of Health & Human Services

**FDA** U.S. Food and Drug Administration  
Protecting and Promoting Your Health

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

Medical Device User Fee

Checkout: Review and Submit Draft Cover Sheet

Cover Sheet	Creation Date	Last Update Date	
<a href="#">FY 2014 Medical Device User Fee Cover Sheet</a> <a href="#">Print/View Draft Cover Sheet</a>	13-JAN-2014 17:19:06	13-JAN-2014 17:26:04	Net: \$3,490.00
			<b>Total: \$3,490.00</b>
<b>Customer Information</b>			
Customer: FDA TEST COMPANY FDA TEST 123-4567889 userfees@fda.gov			
<b>Applicant Contact Information</b>			
Bill To: FDA TEST FDA TEST COMPANY 123 Medical Drive Rockville, USA MD 20850 UNITED STATES			
			<a href="#">Change</a>

[Submit Cover Sheet to FDA](#)

### MDUFA 513g Request for Information Cover Sheet Creation: Step-by-Step Instructions

- 17) 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.

U.S. Department of Health & Human Services  
**FDA** U.S. Food and Drug Administration  
 Protecting and Promoting Your Health

FAQ User Fees Draft Cover Sheet Previous Cover Sheets Profile Logout

Medical Device User Fee

**Confirmation**

YOUR PAYMENT IDENTIFICATION NUMBER IS: **MD6073048-956733**

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 submit a survey. This will only take about 2 minutes to complete.

Cover Sheet	Creation Date	Last Update Date
FY 2014 Medical Device User Fee Cover Sheet <a href="#">Print/View Final Cover Sheet</a>	1 13-JAN-2014 17:19:06	13-JAN-2014 17:26:04
<b>Total:</b>		<b>\$3,490.00</b>

**Customer Information**

Customer: FDA TEST COMPANY  
 FDA TEST  
 123-4567889  
 userfees@fda.gov

**Applicant Contact Information**

Bill To: FDA TEST  
 FDA TEST COMPANY  
 123 Medical Drive  
 Rockville,  
 USA  
 MD 20850  
 UNITED STATES

**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](mailto:userfees@fda.gov).