

'How-To' Guide

Device Facility User Fee Process

October 2008



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'How-To' Guide

Device Facility User Fee Process

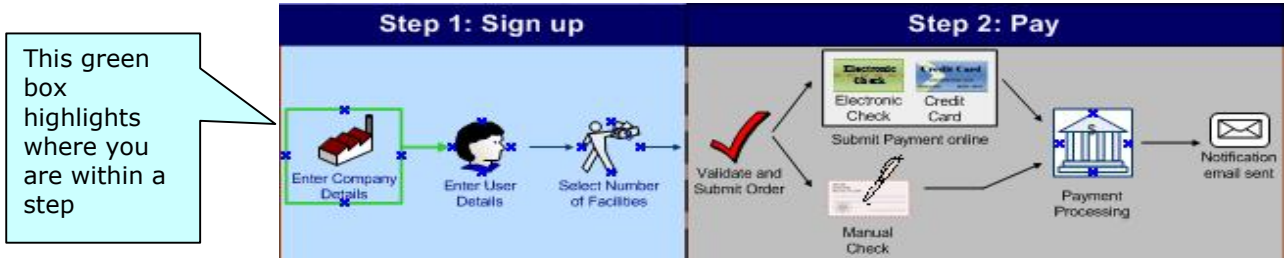
WHAT IS THE PURPOSE OF THIS GUIDE?

On October 1st of 2008, US Food and Drug Administration (FDA) will introduce an improved process for collecting the Device Facility (also known as "establishment") User Fee. As a result, the process you used last year to submit your Device Facility User Fee will change. This Guide contains a step-by-step demonstration of the process and indicates the actions you need to take to make sure you complete the process correctly.

The Device Facility User Fee process does not impact the facilities that are not required to pay the Device Facility User Fee.

How Should I Use This Guide?

The new process contains three major steps. This guide covers the first two steps: Step 1 and Step 2. The image below appears throughout the guide to help you know where you are within each major step. A green box will appear in this image to signal where you are within a step.



The two major steps (Step 1 and Step 2) include "substeps." Substeps simply break down each of the major steps into smaller pieces. Within each substep there are "actions." Actions are the specific tasks you need to complete. For example, an action may tell you to, "Log onto the Device Facility User Fee Website." To further assist you through this process, this guide includes snapshots of what will appear on your screen. The picture below provides an example of a snapshot and its corresponding table of actions.

Substep 1.6: Confirm Quantity of Facility User Fees

This line identifies the substep about which you are reading

This is a snapshot of what will appear on your screen

This number corresponds with the #1 action, as listed in the below table of actions

This number corresponds with the number marked on the above snapshot

This column contains the actions you need to complete in this substep

Action Number	Action
1. <input type="checkbox"/>	<ul style="list-style-type: none"> Review the quantity of Device Facility User Fees you ordered and the Total Due displayed on the screen Click Next
2. <input type="checkbox"/>	You may exit this page at this time, but your payment and registration will remain incomplete. If you decide to exit now, you have 30 days to return to this website and complete your payment.

CONTACT INFORMATION

User Fee Help Desk Email

userfees@fda.gov

User Fee Help Desk Phone Number

(301) 827-9539

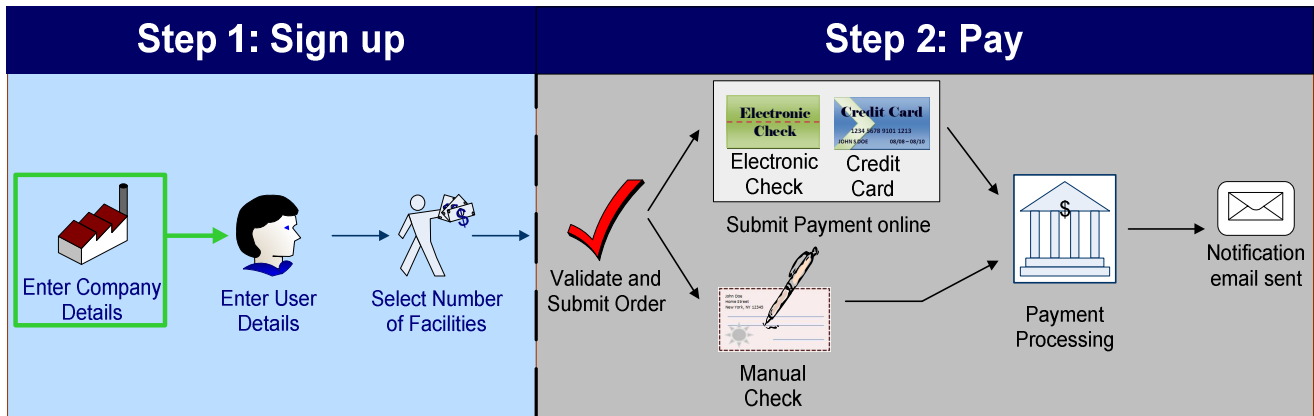
Device Facility User Fee Website

https://fdasfinapp8.fda.gov/OA_HTML/furls.jsp

“Who Must Register” Website

<http://www.fda.gov/cdrh/registration/whomust.html>

STEP 1: SIGN UP



Substep 1.1: Open User Fee Website

Action Number	Action
1. <input type="checkbox"/>	Open the Device Facility User Fee website: https://fdasfinapp8.fda.gov/OA_HTML/furls.jsp .
2. <input type="checkbox"/>	Click the I am here for the first time to pay for my 2009 Establishment Registration Fee selection.
3. <input type="checkbox"/>	Click the Create new Account button once it appears on your screen.

Substep 1.2: Designate Business Information


U.S. Food and Drug Administration


 [FAQ](#)
 [User Fees](#)
 [Sign In](#)

User Account Creation

Business Information

Existing Organization:

Organization Number:

Organization Federal Employer Identification Number:

Organization DUNS:

New Organization

Action Number	Action
1. <input type="checkbox"/>	There are two ways to proceed at this point. Use the following table to select which course of action you need to follow.

If . . .	Then . . .
You have signed up with <u>another</u> FDA user fee site or paid and registered your establishment last year	Skip to Page 8 and complete the actions listed under <i>Access Existing Account</i>
You have <u>not</u> signed up with another FDA user fee site and never paid a user fee before	Skip to Page 9 and complete the actions listed under <i>Create a New Account</i>

Access Existing Account

Existing Organization:

Organization Number:

Organization Federal Employer Identification Number:

Organization DUNS:

New Organization

Action Number	Action
1. <input type="checkbox"/>	<ul style="list-style-type: none"> You have signed up with another FDA user fee site or paid and registered your establishment last year. Therefore, enter one of the following: Organization Number, Organization Federal Employer Identification Number, or Organization DUNS.
2. <input type="checkbox"/>	<ul style="list-style-type: none"> Click Submit.
3. <input type="checkbox"/>	<ul style="list-style-type: none"> Skip to Page 13 and complete the actions listed under <i>Substep 1.5: Enter Quantity of Device Facility User Fees</i>.

Initiate a New Account

FDA U.S. Food and Drug Administration Department of Health and Human Services

FAQ User Fees Sign In

User Account Creation

Business Information

Existing Organization:

Organization Number:

Organization Federal Employer Identification Number:

Organization DUNS:

New Organization

1

2

Action Number	Action
1. <input type="checkbox"/>	<ul style="list-style-type: none"> You have neither signed up with another FDA user fee site nor paid and registered for your establishment last year. Therefore, you need to create a new account. Select New Organization to create a new account.
2. <input type="checkbox"/>	<ul style="list-style-type: none"> Click Submit.

Substep 1.3: Enter Organization/Business Information

U.S. Food and Drug Administration

FAQ User Fees Sign In

User Account Creation

Business Information

* Indicates required field

United States Organization
 Foreign Organization

* Organization Name:

Enter your organization name without any symbols.
Example: Enter "X & Y's Corp. LLP" as "X and Ys Corp LLP"

* Organization Federal Employer Identification Number:

Organization DUNS:

* Country: United States

* Address Line 1:

Address Line 2:

Address Line 3:

Address Line 4:

* City:

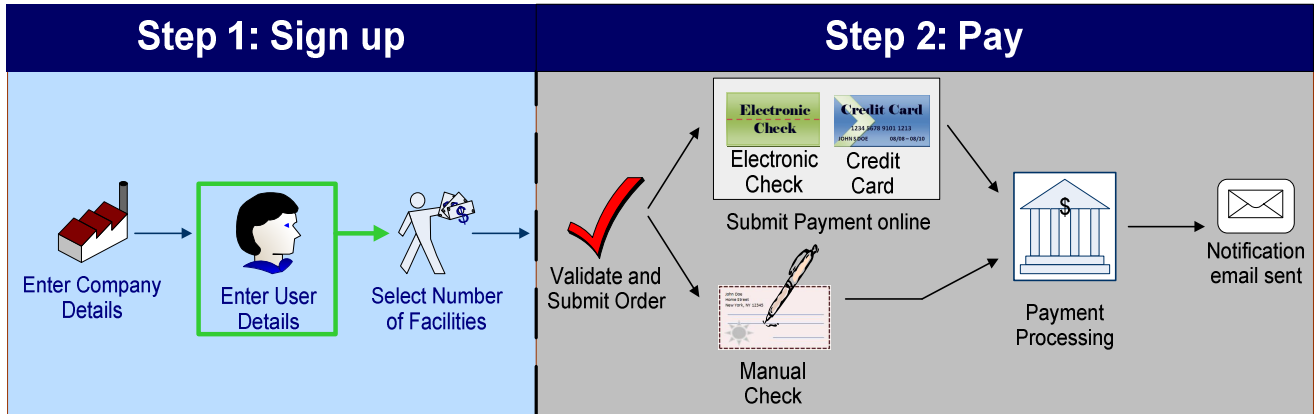
County:

* State:

* Zip:

Submit

Action Number	Action
1. <input type="checkbox"/>	▪ Select United States Organization , or Foreign Organization at the top of the webpage.
2. <input type="checkbox"/>	▪ Enter your <u>organization's</u> information in the remaining fields.
3. <input type="checkbox"/>	▪ Click Submit .



Substep 1.4: Enter User Information

FDA
U.S. Food and Drug Administration

FAQ User Fees Sign In

User Account Creation

User Information
 * Indicates required field

Provide information about your primary point of contact, in case an issue arises with your payment.

* First Name:

Middle Name:

* Last Name:

* Email Address:

* Confirm Email Address:

* Day Phone Number: ()

Evening Phone Number: ()

Fax Number: ()

* User Name:

* Password:

* Confirm Password:

Important Notice: You must provide a valid email address for FDA to reach you regarding any payment issues, refunds, or other notices.

Your user name cannot contain any symbols.

Your password must be at least 8 characters long but cannot repeat any of its characters or contain your user name. Your password must include the following character types: uppercase letters, lowercase letters, numbers, and one of the following symbols: @, #, \$, %, ^, &, * , !

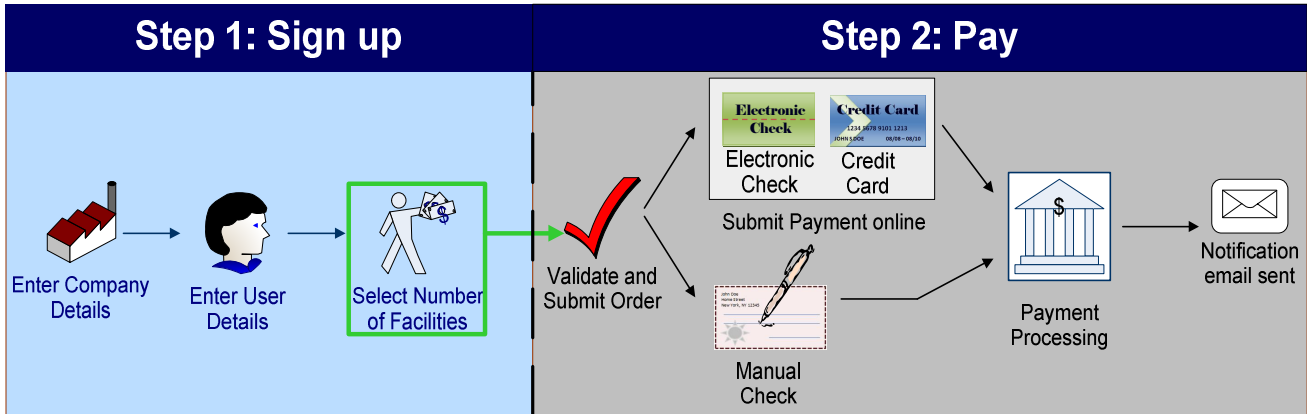
1

2

3

Action Number	Action
1. <input type="checkbox"/>	<ul style="list-style-type: none"> Enter your <u>user</u> contact information in the blank fields.
2. <input type="checkbox"/>	<ul style="list-style-type: none"> Create a username and password. <p>Your username and password here do not have to match your FURLS username and password.</p>
3. <input type="checkbox"/>	<ul style="list-style-type: none"> Click Submit.
4. <input type="checkbox"/>	<ul style="list-style-type: none"> Receive an email from userfees@fda.gov confirming your account creation. The image below is an example of this email. Please store this email in case you forget your username and password in the future.





Substep 1.5: Enter Quantity of Device Facility User Fees

FDA U.S. Food and Drug Administration Department of Health and Human Services

FAQ UserFees Order Previous Orders / PCN Profile Logout

Device Facility User Fee

Device Facility User Fee

On October 1, 2008 FDA introduced an improved process for collecting device facility user fees and registrations. The new process includes 3 main steps:

1. Sign up (you are here)
2. Pay
3. Register

To read more about the new process, please [click here](#).

Begin step 1 by entering the number of facilities for which you are paying. For information about this step, please [click here](#).

You must complete the entire payment and registration process by December 31, 2008. Please provide enough time for payment processing, especially if you are paying by check.

Product	Quantity	Unit Price
Device Facility User Fee	1	\$1,851.00 EACH

Add to Cart

1

2

Action Number	Action
1. <input type="checkbox"/>	▪ Enter the quantity of Device Facility User Fees you need to pay in the Quantity field.
2. <input type="checkbox"/>	▪ Click Add to Cart .

Substep 1.6: Confirm Quantity of Device Facility User Fees

FDA U.S. Food and Drug Administration Department of Health and Human Services

FAQ UserFees Order Previous Orders / PCN Profile Logout

Device Facility User Fee

Order

Do not click the "Back" button in your browser to adjust your quantity. Instead change the number in the "Quantity" field and then click the "Recalculate" button.

Delete	Product	Quantity	Total Due
	Device Facility User Fee	1	\$1,851.00

Recalculate

This order is in progress. Click the "Next" button to continue.

Next

UserFees | Order | Previous Orders / PCN | Profile | Logout

FDA Home Page | Search FDA Site | FDA A-Z Index | Contact FDA | Privacy | Accessibility

FDA Website Management Staff

Action Number	Action
1. <input type="checkbox"/>	<ul style="list-style-type: none"> Review the quantity of Device Facility User Fees you ordered and the Total Due displayed on the screen.
2. <input type="checkbox"/>	<ul style="list-style-type: none"> Click Next. <p>You may exit this page at this time, but your payment and registration will remain incomplete. If you decide to exit now, you have 30 days to return to this website and complete your payment.</p>

Substep 1.7: Review Customer and Contact Information

The screenshot shows the FDA website's 'Billing Information' page. At the top, there is a navigation bar with the FDA logo, the text 'U.S. Food and Drug Administration', and the Department of Health and Human Services logo. Below this is a menu with icons for FAQ, User Fees, Order, Previous Orders / PCN, Profile, and Logout. A 'Device Facility User Fee' button is visible on the right. The main content area is titled 'Billing Information' and contains the following text:

Customer: X AND YS CORP LLP
 Contact: Jane Doe
 123-456-7890
 janedoe@mail.com
 Address:

At the bottom right of the form area, there are two buttons: 'Add / Edit Address' and 'Next'. A green bracket on the left side of the customer and contact information is connected by a green arrow to a green box containing the number '1'. Another green arrow points from a green box containing the number '2' to the 'Add / Edit Address' button.

Action Number	Action
1. <input type="checkbox"/>	<ul style="list-style-type: none"> Review the customer (organization) name and contact information displayed on the screen.
2. <input type="checkbox"/>	<ul style="list-style-type: none"> Click Add/Edit Address to select your billing address.

Substep 1.8: Select Billing Address

Search and Select: Bill to Address

If you do not see the address you are looking for, please select the appropriate country from the list and click the "View All Contacts" button.

Search

Country:

Results

Select	Customer	Contact	Address	Primary	Address Type
<input type="checkbox"/>	X AND YS CORP LLP		100 Street New York, DC 20004 UNITED STATES		

Action Number	Action
1. <input type="checkbox"/>	<ul style="list-style-type: none"> Select your billing address. <p>If your billing address does not appear on the screen, then click Create Address to enter your billing address.</p>
2. <input type="checkbox"/>	<ul style="list-style-type: none"> Click Select.

Substep 1.9: Verify Contact Information

The screenshot shows the FDA User Fees portal. At the top, there is a navigation bar with the FDA logo, the text "U.S. Food and Drug Administration", and the Department of Health and Human Services logo. Below this is a menu with icons for FAQ, User Fees, Order, Previous Orders / PCN, Profile, and Logout. A "Device Facility User Fee" label is visible in the top right corner.

The main content area is titled "Billing Information". It displays the following information:

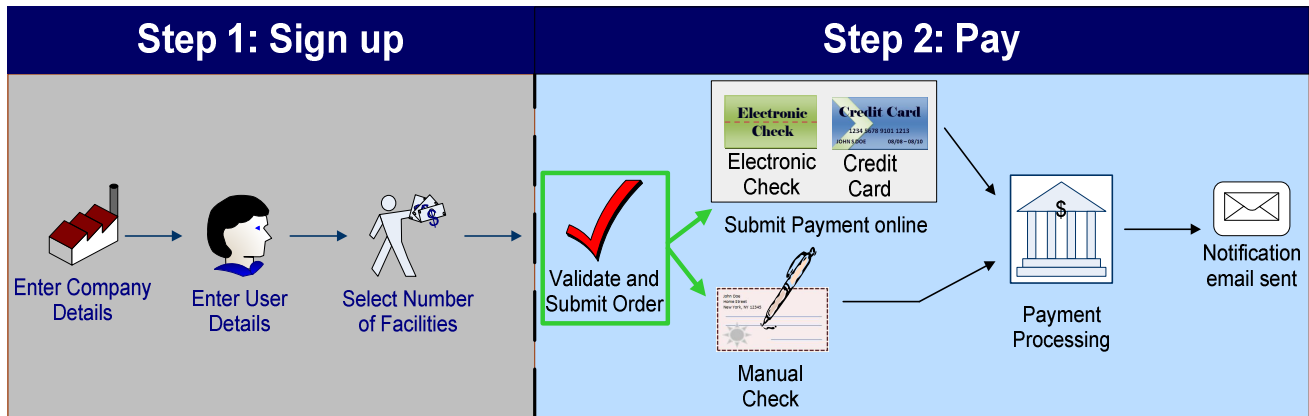
- Customer: X AND YS CORP LLP
- Contact: Jane Doe
123-456-7890
janedoe@mail.com
- Address: 100 Street
New York, DC 20004
UNITED STATES

There are two callouts on the right side of the screenshot:

- 1**: A green arrow points from a box labeled "1" to the contact information.
- 2**: A green arrow points from a box labeled "2" to the "Next" button.

Action Number	Action
1. <input type="checkbox"/>	<ul style="list-style-type: none"> Review your user contact information. To change your billing address, click Add/Edit Address .
2. <input type="checkbox"/>	<ul style="list-style-type: none"> Click Next.

STEP 2: PAY



Substep 2.1: Submit Order

The screenshot shows the 'Submit Order' page on the FDA website. At the top, there are navigation links for FAQ, User Fees, Order, Previous Orders / PCN, Profile, and Logout. The main content area is titled 'Submit Order' and contains a table with the following data:

Product	Quantity	Unit Price
Device Facility User Fee	1	\$1,851.00
		Total: \$1,851.00

Below the table, there is 'Customer Information' and 'Billing Information'. The 'Submit Order' button is located at the bottom right of the form. Green arrows and boxes labeled '1' and '2' indicate the total amount and the submit button, respectively.

Action Number	Action
1. <input type="checkbox"/>	▪ Review your order information.
2. <input type="checkbox"/>	▪ Click Submit Order .

Substep 2.2: View Confirmation

Confirmation
Your order has been submitted electronically. Include your Payment Identification Number (PIN) with your payment.

Product	Quantity	Unit Price
Device Facility User Fee Print/View Final Order	1	\$1,851.00

Total: \$1,851.00

YOUR PAYMENT IDENTIFICATION NUMBER (PIN) IS:
50000015

[Pay Now](#) [Create Another Order](#)

[What are my payment options?](#)

Action Number	Action
1. <input type="checkbox"/>	<ul style="list-style-type: none"> Review your confirmation information and, most importantly, note your Payment Identification Number (PIN) listed in the middle of the screen. <p>Your PIN is exactly as its name implies: it is a number that identifies your payment. Although you receive your PIN at this step, you have not completed your payment yet.</p>
2. <input type="checkbox"/>	<ul style="list-style-type: none"> Click Print/View Final Order to print your order page.

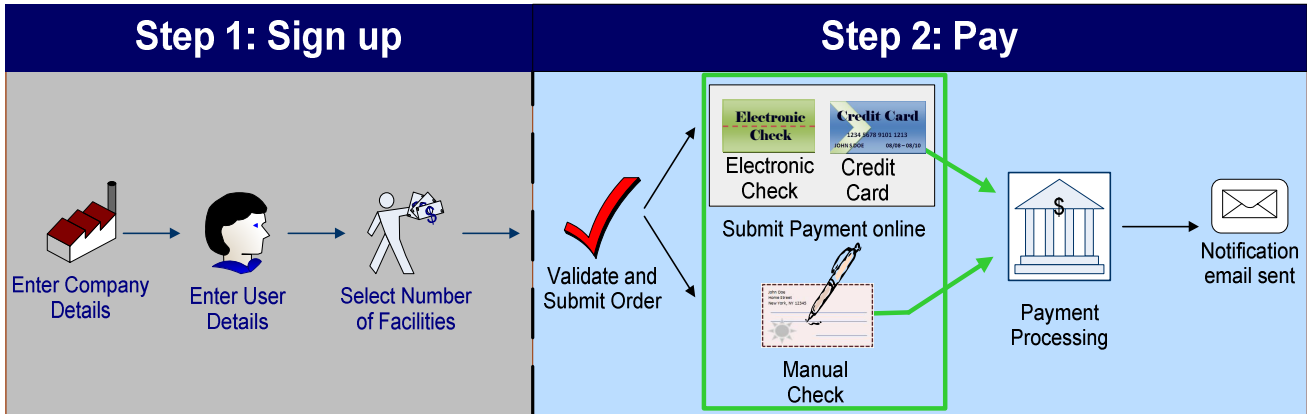
Substep 2.3: View Order Page

Form Approved, OMB No. 0910-0625 Expiration Date: January 31, 2009. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION DEVICE FACILITY USER FEE	PAYMENT IDENTIFICATION NUMBER: 50000015 Include the Payment Identification Number (PIN) with payment.
The following actions must be taken to properly submit your payment: 1. To submit payment, please select one of the following options: A. To pay electronically using ACH (electronic check from a US bank) or a credit card, please select the "Pay Now" option. B. To pay using a check drawn on a US bank in US dollars, please follow these instructions: <ul style="list-style-type: none"> • Make check payable to the Food and Drug Administration • Write the Payment Identification Number (PIN) on the check • Mail check and printed copy of the order to: Food and Drug Administration P.O. Box 70961... Charlotte, NC 28272-0961. or <ul style="list-style-type: none"> • For checks sent by courier, mail the check and printed copy of the order to: Wachovia Bank Attn: Food and Drug Administration Lockbox 70961... 1525 West W.T. Harris Blvd., Room NC0810 Charlotte, NC 28262 <i>Note: This Wachovia Bank address is for courier delivery only; do not send mail to this address.</i> C. To pay by wire transfer, please contact the User Fee helpdesk at userfees@fda.gov for instructions.	
2. Company Name and Address X AND Y's CORP LLP 100 Street New York, DC 20004 US 2.1 Employer Identification Number (EIN) 129078321	3. Contact Name Jane Doe 3.1 E-mail Address janedoe@mail.com 3.2 Telephone Number 100-987-1234 3.3 Fax Number
4. PIN-PCN (Payment Identification Number-Payment Confirmation Number):	
5. Amount Due: \$1,851.00	
Close Window Print Order	

Form FDA 3601 (01/2007)

Action Number	Action
1. <input type="checkbox"/>	<ul style="list-style-type: none"> ▪ Review the order page that appears; it presents your order information and your PIN. This screen also provides direction on how to complete your payment. Note: Although you receive your PIN at this step, you have not completed your payment yet.
2. <input type="checkbox"/>	<ul style="list-style-type: none"> ▪ Click Print to print this screen.
3. <input type="checkbox"/>	<ul style="list-style-type: none"> ▪ Click Close to close this screen.



Substep 2.4: Select a Payment Method

Action Number	Action
1. <input type="checkbox"/>	There are multiple ways to proceed at this point. Use the following table to select which course of action you need to follow.

If . . .	Then . . .
You want to pay for your order online with a credit card or by electronic check (ACH)	Skip to Page 22 and complete the actions listed under <i>Pay Online With Credit Card or Electronic Check</i>
You want to pay for your order by paper check	Skip to Page 28 and complete the actions listed under <i>Pay by Paper Check</i>

Pay Online With Credit Card or Electronic Check

System Message

- The system has populated the Payment Date with the next available payment date.

Online Payment [Return to your originating application](#)

Step 1: Enter Payment Information 1 | 2 | 3

This item is payable by [Bank Account Debit \(ACH\)](#) or [Plastic Card \(ex. VISA, Mastercard, American Express, Diners Club, Discover\)](#)

Option 1: Pay Via Bank Account (ACH) [About ACH Debit](#)

Required fields are indicated with a red asterisk *

Account Holder Name:

Payment Amount: \$1,851.00

Account Type:

Routing Number:

Account Number:

Confirm Account Number:

Check Number:

Routing Number: 269467630 Account Number: 9243767390 Check Number: 1234

Payment Date: 08/11/2008

Select the "Continue with ACH Payment" button to continue to the next step in the ACH Debit Payment Process.

[Continue with ACH Payment](#) [Cancel](#)

Note: Please avoid navigating the site using your browser's Back Button - this may lead to incomplete data being transmitted and pages being loaded incorrectly. Please use the links provided whenever possible.

Option 2: Pay Via Plastic Card (PC) (ex: VISA, Mastercard, American Express, Diners Club, Discover)

Required fields are indicated with a red asterisk *

Account Holder Name:

Payment Amount: \$1,851.00

Billing Address:

Billing Address 2:

City:

State / Province:

Zip / Postal Code:

Country: United States

Card Type:

Card Number:

Security Code:

Expiration Date:

Select the "Continue with Plastic Card Payment" button to continue to the next step in the Plastic Card Payment Process.

[Continue with Plastic Card Payment](#) [Cancel](#)

Note: Please avoid navigating the site using your browser's Back Button - this may lead to incomplete data being transmitted and pages being loaded incorrectly. Please use the links provided whenever possible.

- 1**
(Electronic Check)
- 2**
(Electronic Check)
- 1**
(Credit Card)
- 2**
(Credit Card)

Action Number	Action
1. <input type="checkbox"/>	<ul style="list-style-type: none"> Enter your credit card or electronic check information.
2. <input type="checkbox"/>	<ul style="list-style-type: none"> Click on the appropriate confirmation button, either Continue with ACH Payment or Continue with Plastic Card Payment, depending on your selected payment method. <p>Please note: a credit card is the same thing as a "plastic card."</p>

Authorize Online Payment

Online Payment [Return to your originating application](#)
 Step 2: Authorize Payment 1 | 2 | 3

Payment Summary [Edit this information](#)

Address Information	Account Information	Payment Information
Account Holder Name: X AND YS CORP Billing Address: Billing Address 2: City: State / Province: Zip / Postal Code: Country: USA	Card Type: Master Card Card Number: *****5100 Expiration Date: 1 / 2010	Payment Amount: \$1,851.00 Transaction Date 08/08/2008 10:17 and Time: EDT

Email Confirmation Receipt
 To have a confirmation sent to you upon completion of this transaction, provide an email address and confirmation below.

Email Address:

Confirm Email Address:

CC: Separate multiple email addresses with a comma

Authorization and Disclosure
 Required fields are indicated with a red asterisk *

I authorize a charge to my card account for the above amount in accordance with my card issuer agreement. *

Press the "Submit Payment" Button only once. Pressing the button more than once could result in multiple transactions.

Note: Please avoid navigating the site using your browser's Back Button - this may lead to incomplete data being transmitted and pages being loaded incorrectly. Please use the links provided whenever possible.

1

2

3

Action Number	Action
1. <input type="checkbox"/>	<ul style="list-style-type: none"> Review your payment information on the displayed screen.
2. <input type="checkbox"/>	<ul style="list-style-type: none"> Enter your email address to have a confirmation of your payment sent to you once FDA processes your payment.
3. <input type="checkbox"/>	<ul style="list-style-type: none"> Click Submit Payment. <p>A payment is not complete until FDA processes it. Even though you may click Submit at this point to submit your payment, your payment is not <i>complete</i> until FDA processes it. Processing typically takes two to three business days.</p>

Review Confirmation of Online Payment

The screenshot shows a payment confirmation page titled "Online Payment Step 3: Confirm Payment". It includes a thank you message, tracking information, and a payment summary table. A green box with the number "1" points to the "Print this window" link. Another green box with the number "2" points to the "Return to your agency website" link at the bottom.

1

Online Payment
Step 3: Confirm Payment 1 | 2 | 3

Thank you.
Your transaction has been successfully completed.
It is recommended you [print a copy](#) for your records. [Print this window.](#)

Pay.gov Tracking Information
Application Name: FDA USER FEES
Pay.gov Tracking ID: 3FOCDJO
Agency Tracking ID: 50000146
Transaction Date and Time: 08/08/2008 10:18 EDT

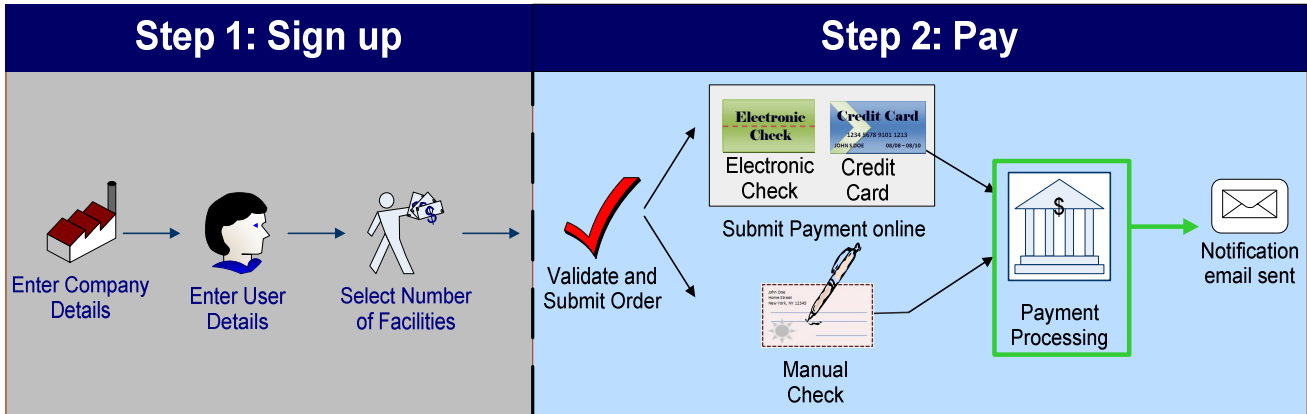
Payment Summary

Address Information	Account Information	Payment Information
Account Holder Name: X AND YS CORP	Card Type: Master Card	Payment Amount: \$1,851.00
Billing Address:	Card Number: *****5100	Transaction Date 08/08/2008 10:18 and Time: EDT
Billing Address 2:	Expiration Date: 1 / 2010	
City:		
State / Province:		
Zip / Postal Code:		
Country: USA		

[Return to your agency website](#)

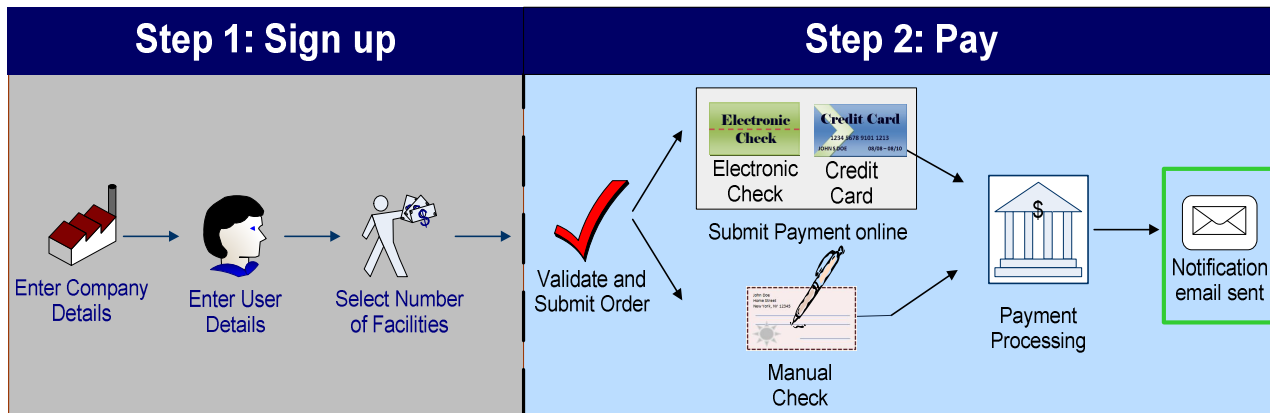
2

Action Number	Action
1. <input type="checkbox"/>	<ul style="list-style-type: none"> Review your payment information. You may print this screen by clicking on print a copy or Print this window.
2. <input type="checkbox"/>	<ul style="list-style-type: none"> Click Return to your agency website.

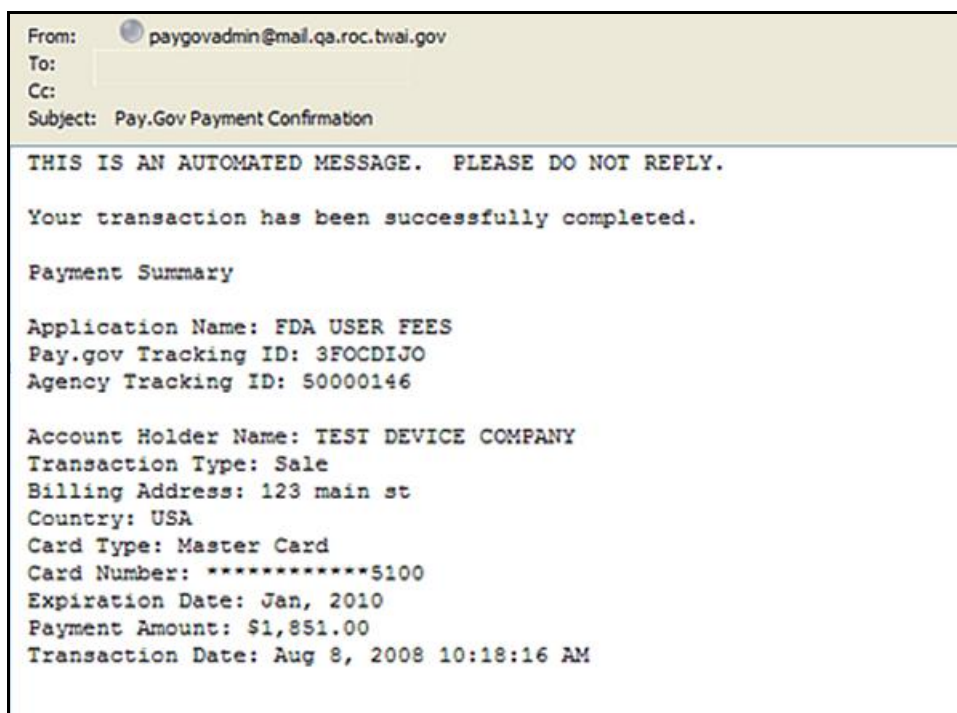


Substep 2.5: Track Orders

Action Number	Action
1. <input type="checkbox"/>	<ul style="list-style-type: none"> Review your payments on this screen. The payment you just created appears under the "Results" section.

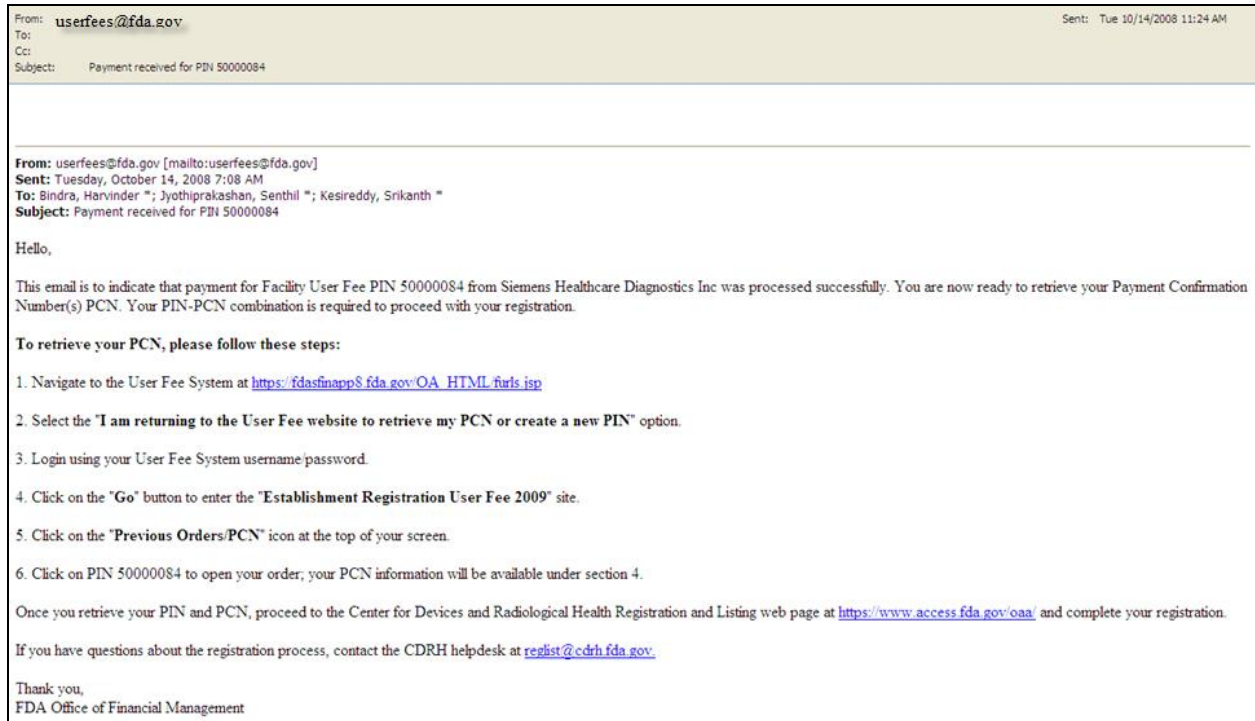


Substep 2.6: Receive Payment Confirmation Email



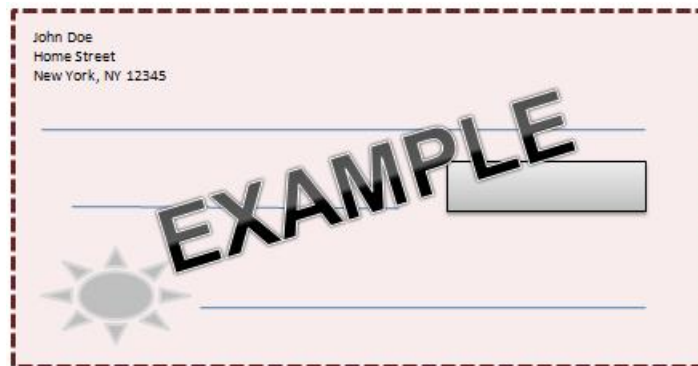
Action Number	Action
1. <input type="checkbox"/>	<ul style="list-style-type: none"> Receive an email (after you submit your payment) from pay.gov. This email tells you that your payment was received by pay.gov. The above image is an example of this email. <p>Please note that your payment is still not complete; FDA is processing your payment and will send you an additional email once your payment is complete.</p>

Substep 2.7: Receive Successful Payment Email

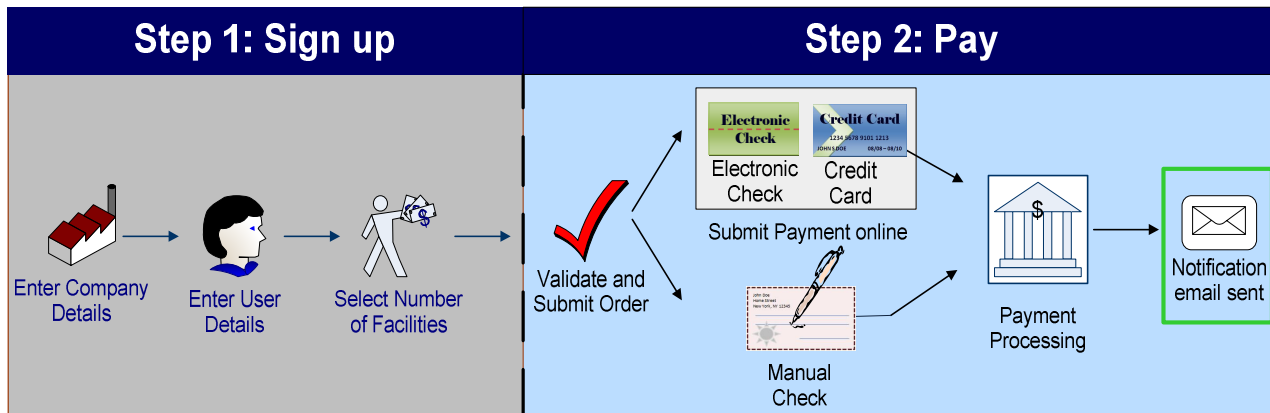


Action Number	Action
1. <input type="checkbox"/>	<ul style="list-style-type: none"> Receive an email from FDA. This email tells you that your payment was successfully processed by FDA. This email tells you that your payment is complete and includes instruction on how to access your PCN. The above image is an example of this email.
2. <input type="checkbox"/>	<ul style="list-style-type: none"> You are done paying for your Device Facility User Fee. Follow the instructions in the email to register your facility with FDA.

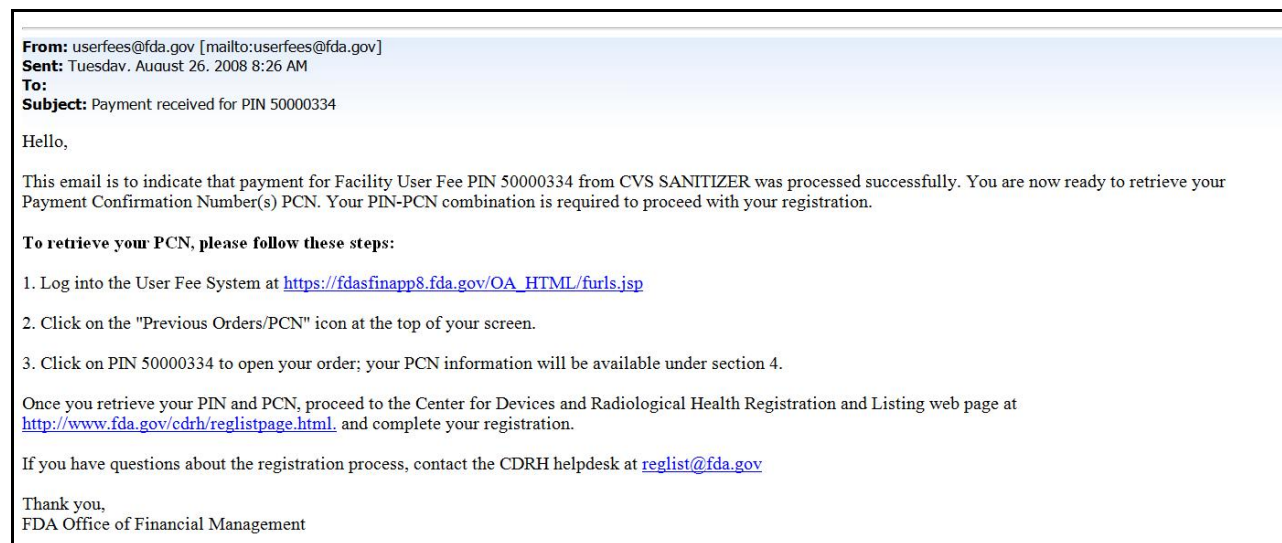
Pay by Paper Check



Action Number	Action
<p>1. <input type="checkbox"/></p>	<ul style="list-style-type: none"> ▪ To pay with a paper check, mail your paper check to: <p style="text-align: center;">Food and Drug Administration P.O. Box 70961 Charlotte, NC 28272-0961</p> ▪ When sending by courier, mail your check and order to: <p style="text-align: center;">Wachovia Bank Attn: Food and Drug Administration Lockbox 70961 1525 West WT Harris Blvd., Room NC0810 Charlotte, NC 28262</p> <p>Make sure to write your PIN number on your paper check.</p>



Substep 2.5: Receive Successful Payment Email



Action Number	Action
1. <input type="checkbox"/>	<ul style="list-style-type: none"> Receive an email from FDA. This email tells you that your payment was successfully processed by FDA. This email tells you that your payment is complete and includes instruction on how to access your PCN. The above image is an example of this email.
2. <input type="checkbox"/>	<ul style="list-style-type: none"> You are done paying for your Device Facility User Fee. Follow the instructions in the email to register your facility with FDA.