



[FDA Home Page](#) | [Contact CBER On-Line Technical Support](#)

CBER On-Line - Login Screen

AS OF 03/15/2019 FDA'S SECURITY POLICY REQUIRES YOU TO RESET YOUR PASSWORD TO RETAIN ACCESS EVERY 60 DAYS

Use the CBER On-line system to make these electronic submissions online:
Blood Establishment Registration
Tissue Establishment Registration
Biological Product Deviation Reporting (Form FDA 3486)

New CBER On-Line Users
New users must first create an account. [Create a New Account.](#)

Existing account holders may login by entering your user name and password below.

<input type="button" value="Create New Account"/>	*User Name: <input type="text"/>	
<input type="button" value="See Instructions"/>	*Password: <input type="text"/>	Forgot your User Name or Password?
<input type="button" value="Contact Support"/>	*Application: <input type="text" value="CBER On-Line - Main Menu"/>	▼

REMINDER: User Names and Passwords are CASE SENSITIVE

- You are accessing a U.S. Government information system, which includes (1) this computer, (2) this computer network, (3) all computers connected to this network, and (4) all devices and storage media attached to this network or to a computer on this network. This information system is provided for U.S. Government-authorized use only.
- Unauthorized or improper use of this system may result in disciplinary action, as well as civil and criminal penalties.
- By using this information system, you understand and consent to the following:
 - You have no reasonable expectation of privacy regarding any communication or data transiting or stored on this information system. At any time, and for any lawful Government purpose, the government may monitor, intercept, and search and seize any communication or data transiting or stored on this information system.
 - Any communication or data transiting or stored on this information system may be disclosed or used for any lawful Government purpose.

*I understand.

*Required

[Help](#)

Electronic Human Cells and Tissue Establishment Registration System (eHCTERS)

Activity Selection Screen

eHCTERS - Activity Selection
Welcome UserName
All establishments that manufacture human cells, tissues, or cellular or tissue-based products (HCT/Ps) regulated solely under Section 361 of the Public Health Service Act and 21 CFR Part 1271 must use eHCTERS to register and list their HCT/Ps with FDA. Manufacture means any or all steps in the recovery, processing, storage, labeling, packaging, or distribution of any HCT/P, and the screening or testing of a cell or tissue donor. After we receive your registration and HCT/P listing information, we will update our records.
Electronic Form Instructions
Select the activity you wish to complete from the list below. If this is your establishment's first time submitting an HCT/P registration, please select Initial Registration. If you would like to edit previously submitted registration and HCT/P listing information, please select Edit Registration Information. If you are returning to work on a previously saved but not submitted registration, select Complete Unfinished Registration and enter the corresponding Pre-Confirmation number. When you have made your selection and entered the requested information, press the Continue button to proceed.
<input type="radio"/> Initial Registration: Select this if your establishment is submitting registration information for the first time.
<input checked="" type="radio"/> Edit Registration Information: Select this if you have the FEI number assigned to your establishment.
Reason for Submission: <input type="radio"/> Annual Registration/Listing <input type="radio"/> Change in Information <input type="radio"/> In-Activate Registration
Select from your existing user establishments: <input type="button" value="v"/>
If your establishment does not appear in the above drop down list, press the User Establishments button below to add your establishment to the list
<input type="radio"/> Complete Unfinished Registration: Pre-Confirmation Number must be provided. <input type="text"/>
<input type="button" value="Continue"/> <input type="button" value="User Establishments"/> <input type="button" value="Active Users"/> <input type="button" value="CBER On-Line Main Menu"/>

User Establishments Screen

eHCTERS - User Establishments			
Enter the FEI number of the establishment to which you are requesting access.			
		*FEI:	<input style="width: 100px;" type="text"/>
		*Last Registration Receipt Date (MM/DD/YYYY):	<input style="width: 100px;" type="text"/>
* Required	<input type="button" value="Add This Establishment"/>	<input type="button" value="Return to Activity Selection Screen"/>	
	<input type="button" value="Clear Screen"/>	<input type="button" value="CBER On-Line Main Menu"/>	
This Profile is currently subscribed to the following establishments:			
	Current Establishments	Location	FEI

Active Users Screen

eHCTERS - Active Users			
<input type="button" value="Return to Activity Selection Screen"/>			
Current User: UserName			
The following table lists all Users associated with the same facilities as the current user.			
	Current Establishments	FEI	User Name
	Real Name		
10162018 Test		4005550091	UserName

Submissions Pending Screen

eHCTERS - Submissions Pending

Current User: UserName

This page is being displayed because Other submissions are pending for this facility. If you experience problems with this Web Site Contact: HCT/P Registration Coordinator.

10162018 Test
FEI: 4005550091

[Edit P-36410](#)

Created By: (10/18/2018)
Not Submitted, Last Modified by: (10/18/2018)

[View P-36411](#)

Created By: (10/18/2018)
Submitted By: (10/18/2018)

[Return to Activity Selection Screen](#)

[Create a New Registration Submission](#)

Initial Establishment Registration Information Screen

FEI:										Pre-Confirmation Number: 37148	
Legal Name:										Todays Date: 10/24/2018	
Registration	Address	Reporting Official	U.S. Agent	Importer	HCT/P Listing	Function	Donor	Additional Info	Report	Save	

eHCTERS - Initial Establishment Registration Information

*** Reason for Submission**

Initial Registration

Other FDA Registrations for the entered FEI Number

<input type="checkbox"/> Blood	<input type="text"/>
<input type="checkbox"/> Devices	<input type="text"/>
<input type="checkbox"/> Drug	<input type="text"/>

*** Required**

Edit Establishment Registration Information Screen

FEI: 3003003000										Pre-Confirmation Number: 37151	
Legal Name: FDA Tissue Test										Todays Date: 10/24/2018	
Registration	Address	Reporting Official	U.S. Agent	Importer	HCT/P Listing	Function	Donor	Additional Info	Report	Save	

eHCTERS - Edit Establishment Registration Information

*** Reason for Submission**

Annual Registration/Listing
 Change in Information

Tissue FEI# 3003003000

Other FDA Registrations for the entered FEI Number

<input type="checkbox"/> Blood	<input type="text"/>
<input type="checkbox"/> Devices	<input type="text"/>
<input type="checkbox"/> Drug	<input type="text"/>

*** Required**

Establishment Registration Address Information Screen

FEI:						Pre-Confirmation Number: 37152				
Legal Name:						Todays Date: 10/24/2018				
Registration	Address	Reporting Official	U.S. Agent	Importer	HCT/P Listing	Function	Donor	Additional Info	Report	Save

eHCTERS - Establishment Address Information

Physical Location

* Legal Name

* Street Address

* City

* U.S. State * Postal Code

* Country

* Phone(xxx-xxx-xxxx) ext.

Foreign Phone(Country Code-City Code-Telephone Number)

Satellite Recovery Establishment If checked, please enter Parent Manufacturing Establishment FEI

Parent Manufacturing Establishment FEI No.

Testing For Micro-Organisms Only

* Required

Possible Establishment Matches Found Screen

FEI:
Legal Name: FDA Tissue Test

Pre-Confirmation Number: 37152
Todays Date: 10/24/2018

eHCTERS - Possible Establishment Matches Found

Your establishment may already be registered. Please review the list of possible matches below. You may view detailed information about each establishment by clicking the establishment name.

- If your establishment is not listed, continue with the initial registration.
- If your establishment is listed below as:
 - **Pre-Registered**, your establishment registration is still under review. Please discontinue the initial registration and contact tissuereg@fda.hhs.gov regarding the status of your registration.
 - **Registered**, your establishment is already registered. Please discontinue the initial registration and follow the instructions on the Activity Selection page if you wish to edit your registration.
 - **Inactive**, your establishment information is in the system but your establishment is not currently registered. Please discontinue the initial registration and follow the instructions on the Activity Selection page if you wish to "edit and reactivate" your registration.
- If Registered or Inactive: After discontinuing your initial registration the system will navigate to the Activity Selection page. If you wish to edit your registration, select Edit Validated Form, select Change in Information, select your establishment and then press continue.

Establishment Name	City, State/Zip	FEI	Establishment Status
EDA Tissue Test	Rockville, MD / 20852	3003003000	Pre-registered

Establishment Reporting Official Information Screen

FEI:		Pre-Confirmation Number: 37155								
Legal Name:		Todays Date: 10/24/2018								
Registration	Address	Reporting Official	U.S. Agent	Importer	HCT/P Listing	Function	Donor	Additional Info	Report	Save

eHCTERS - Establishment Reporting Official Information

Reporting Official Information

*First Name M.I.

*Last Name

Credentials

*Title

*E-Mail Address

*Phone(xxx-xxx-xxxx) Ext.

Foreign Phone(Country Code-City Code-Telephone Number)

Mailing Address

*Institution Name

*Street Address

*City

*State

*Postal Code

*Country

* Required

Establishment U.S. Agent Information Screen

FEI: _____ Pre-Confirmation Number: 37156
Legal Name: _____ Todays Date: 10/24/2018

Registration Address Reporting Official U.S.Agent Importer HCT/P Listing Function Donor Additional Info Report Save

eHCTERS - Establishment U.S. Agent Information

U.S. Agent Information

*First Name M.I.
*Last Name
Credentials
Title
*E-Mail Address
*Phone(XXX-XXX-XXXX) Ext.
Foreign Phone(Country Code-City Code-Telephone Number)

Mailing Address

Organization Name
*Street Address

*City
*State *Postal Code

* Required

Add Another U.S. Agent

Next Previous Select New Establishment CBER On-Line Main Menu

Establishment Importer Information Screen

FEI: _____ Pre-Confirmation Number: 37156
Legal Name: _____ Todays Date: 10/24/2018

[Registration](#) | [Address](#) | [Reporting Official](#) | [U.S. Agent](#) | [Importer](#) | [HCT/P Listing](#) | [Function](#) | [Donor](#) | [Additional Info](#) | [Report](#) | [Save](#)

eHCTERS – Establishment Importer Information

Your establishment is located outside the United States. Please provide information on any importer (defined in 21 CFR 1271.3(mm)) that is known to you. Otherwise, you may advance to the HCT/P Listing tab.

Importer Organization

*Importer First Name M.I.

*Importer Last Name

*Street Address

*City

*State *Postal Code

*Phone(XXX-XXX-XXXX) Ext.

*E-Mail Address

* Required

[Add Another Importer](#)

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HCT/P Listing Information Screen

FEI: _____ Pre-Confirmation Number: 37156
 Legal Name: _____ Today's Date: 10/24/2018

eHCTERS - HCT/P Listing Information

Types of HCT/Ps	HCT/Ps Described in 21 CFR 1271.10	Date of Discontinuance (mm/dd/yyyy)	Date of Resumption (mm/dd/yyyy)	Proprietary Names
Amniotic Membrane	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	
Blood Vessel	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	
Bone	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	
Cardiac Tissue - non-valved	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	
Cartilage	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	
Cornea	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	
Dura Mater	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	
Embryo	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	
Fascia	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	
Heart Valve	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	
HPC Apheresis	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	
HPC Cord Blood	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	
Ligament	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	
Nerve Tissue	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	
Oocyte	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	
Ovarian Tissue	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	
Pancreatic Islet Cells - autologous	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	
Parathyroid	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	
Pericardium	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	
Peripheral Blood Mononuclear Cells	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	
Peritoneal Membrane	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	
Sclera	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	
Semen	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	
Skin	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	
Tendon	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	
Testicular Tissue	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	
Teeth Pulp	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	
Umbilical Cord Tissue	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	

Function Information Screen

FEI: _____ Pre-Confirmation Number: 37156
 Legal Name: _____ Todays Date: 10/24/2018

Registration | Address | Reporting Official | U.S. Agent | Importer | HCT/P Listing | Function | Donor | Additional Info | Report | Save

eHCTERS - HCT/P Listing - Function Information

Types of HCT/Ps	Recover	Screen	Donor Testing	Package	Process	Store	Label	Distribute
Amniotic Membrane								
Blood Vessel								
Bone								
Cardiac Tissue - non-valved								
Cartilage								
Cornea								
Dura Mater								
Embryo								
Fascia								
Heart Valve								
HPC Apheresis								
HPC Cord Blood								
Ligament								
Nerve Tissue								
Oocyte								
Ovarian Tissue								
Pancreatic Islet Cells - autologous								
Parathyroid								
Pericardium								
Peripheral Blood Mononuclear Cells								
Peritoneal Membrane								
Sclera								
Semen								
Skin								
Tendon								
Testicular Tissue								
Tooth Pulp								
Umbilical Cord Tissue								

Next | Previous | Select New Establishment | CBER On-Line Main Menu

Donor Information Screen

FEI:							Pre-Confirmation Number: 37156			
Legal Name:							Today's Date: 10/24/2018			
Registration	Address	Reporting Official	U.S. Agent	Importer	HCT/P Listing	Function	Donor	Additional Info	Report	Save

eHCTERS - HCT/P Listing - Donor Information

Types of HCT/Ps	SIP	Directed	Anonymous	Autologous	Family Related
Embryo					
HPC Apheresis					
HPC Cord Blood					
Oocyte					
Peripheral Blood Mononuclear Cells					
Semen					

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Additional Information to Complete HCT/P Information Listing Screen

FEI:							Pre-Confirmation Number: 37157			
Legal Name:							Today's Date: 10/24/2018			
Registration	Address	Reporting Official	U.S. Agent	Importer	HCT/P Listing	Function	Donor	Additional Info	Report	Save

eHCTERS - Additional Information to Complete HCT/P Listing

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Reporting Official Signature Screen

eHCTERS - Reporting Official Signature	
Current User: Date: 10/24/2018	
By entering your Reporting Official E-Mail Address and continuing with your submission of this information to FDA/CBER, you are certifying that:	
<ol style="list-style-type: none">1. You are the Reporting Official as listed in this form ()2. As a Reporting Official, you are the person appointed by the owner or operator to register the firm and answer all correspondence and inquiries relative there to.3. All information contained in this form is true and accurate to the best of your knowledge.	
Under 21 CFR 1271.25 (a)(4), a dated signature by the reporting official affirms that all information contained in the establishment registration and HCT/P listing form is true and accurate, to the best of his or her knowledge.	
Additionally, under 21 CFR 1271.25(b), you state that each listed HCT/P meets the criteria set out in section 1271.10.	
Under 18 USC 1001, anyone who knowingly and willfully makes a materially false, fictitious, or fraudulent statement or representation to the U.S. Government is subject to criminal penalties.	
If you understand and agree to the above statements, re-enter your Reporting Official E-Mail Address then press the Continue button. You may press the Cancel button if you do not wish to continue.	
Confirm Reporting Official E-Mail Address:	<input type="text"/> <input type="button" value="Continue"/> <input type="button" value="Cancel"/>

Submitted Establishment Registration Information Screen

PLEASE NOTE:
The changes submitted today will not be reflected in the electronic Tissue Establishment Registration (eHCTERS) until they are validated by the FDA. This process varies in time. Please Contact the Tissue Establishment Registration coordinator if you have any questions.

Registration Summary Report Provided to the Establishments (Example-Page 2)

Additional Information: No additional information provided.

Proprietary Name(s):

For Non U.S. Establishments Only:

U.S. Agent(s):

Name and Organization	Address	Phone and Email

Importer(s):

Name and Organization	Address	Phone and Email
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