

CBER On-Line- Login Screen



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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

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.

Create New Account	*User Name:	
See Instructions	*Password:	Forgot your User Name or Password?
Contact Support	*Application: 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.

LOGIN

*Required

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CBER On-Line Version 1.15.01
Page Updated 07/23/2021

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FDA / Center for Biologics Evaluation and Research

CBER On-Line Main Menu Screen

**U.S. FOOD & DRUG
ADMINISTRATION**

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CBER On-Line - Main Menu

Production Applications	Welcome to CBER On-Line
Blood Establishment Registration (eBER)	
HCT/P Establishment Registration (eHCTERS)	

Exit CBER On-Line Application

Edit Current Account

Change Password

CBER On-Line Version 1.15.02
Page Updated 07/23/2021

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Note: After eHCTERS application is selected, the OMB control number and expiration date are displayed on all subsequent pages (see next page for an example).

Electronic Human Cells and Tissue Establishment Registration System (eHCTERS)

Activity Selection Screen (screenshot of the entire page)

FDA U.S. FOOD & DRUG ADMINISTRATION

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eHCTERS - Activity Selection

Last Session Login: 06/27/2023 12:55:20

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.

☐ **Initial Registration:** Select this if your establishment is submitting registration information for the first time.

☒ **Edit Registration Information:** Select this if you have the FEI number assigned to your establishment.

Reason for Submission: ☐ Annual Registration/Listing ☐ Change in Information ☐ In-Activate Registration

Select from your existing user establishments:

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

☐ **Complete Unfinished Registration:** Pre-Confirmation Number must be provided.

[Continue](#) [User Establishments](#) [Active Users](#) [CBER On-Line Main Menu](#)

DEPARTMENT OF HEALTH AND HUMAN SERVICES, FOOD AND DRUG ADMINISTRATION
ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS,
TISSUES AND CELLULAR AND TISSUE-BASED PRODUCTS (eHCTERS)

eHCTERS v02.13.01
Updated 11/20/2020

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The text highlighted in yellow will be replaced with:

OMB Control Number 0910-0543; Expiration Date 07/31/2023

See [OMB Burden Statement](#)

The hyperlink will lead to this text:

OMB Burden Statement

Public reporting burden for this collection of information is estimated as follows:

The time required to complete registration and listing for existing establishments is estimated to average **30 minutes** per response, for new establishments it is estimated to average **45 minutes** per response, and updates to a list are estimated to average **30 minutes** per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information.

Send comments regarding this burden estimate or any other aspects of this collection of information, including suggestions for reducing burden, to PRAStaff@fda.hhs.gov.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

User Establishments Screen

eHCTERS - User Establishments

Enter the FEI number of the establishment to which you are requesting access.

*FEI:

*Last Registration Receipt Date (MM/DD/YYYY):

* Required

Add This Establishment	Return to Activity Selection Screen
Clear Screen	CBER On-Line Main Menu

This Profile is currently subscribed to the following establishments:

	Current Establishments	Location	FEI
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Active Users Screen

eHCTERS - Active Users

Return to Activity Selection Screen

Current User: i

The following table lists all Users associated with the same facilities as the current user.

Current Establishments	FEI	User Name	Real Name
Test Valley Research	3011002748		

Submissions Pending Screen

eHCTERS - Submissions Pending

Current User: |

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.](#)

Test Valley Research
FEI: 3011002748

Edit P-54827

Created By: () (10/11/2022)
Not Submitted, Last Modified by: () (10/11/2022)

Return to Activity Selection Screen

Create a New Registration Submission

Initial Establishment Registration Information Screen

FEI:										Pre-Confirmation Number: 55293	
Legal Name:										Today's Date: 10/14/2022	
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							
				☐ Blood							
				☐ Devices							
				☐ Drug							
* Required											
Next			Select New Establishment				CBER On-Line Main Menu				

Edit Establishment Registration Information Screen

FEI: 3011002748										Pre-Confirmation Number: 54827	
Legal Name: Test Valley Research										Today's Date: 10/14/2022	
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				Tissue FEI#		3011002748					
☒ Annual Registration/Listing				Other FDA Registrations for the entered FEI Number							
☐ Change in Information				☐ Blood							
				☐ Devices							
				☐ Drug							
* Required											
Next			Select New Establishment				CBER On-Line Main Menu				

Establishment Registration Address Information Screen

FEI:										Pre-Confirmation Number: 55294	
Legal Name:										Today's Date: 10/14/2022	
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: Test facility

Pre-Confirmation Number: 55291

Today's Date: 10/12/2022

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
Test facility	test city, MD / 20879		Pre-registered

[CONTINUE WITH INITIAL REGISTRATION](#)

[DISCONTINUE INITIAL REGISTRATION](#)

FEI:		Pre-Confirmation Number: 55294								
Legal Name:		Today's Date: 10/14/2022								
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

Copy From Address Info Screen

*City

*State None ▼ *Postal Code

*Country UNITED STATES ▼

* Required

Next
Previous
Select New Establishment
CBER On-Line Main Menu

Establishment U.S. Agent Information Screen

FEI:

Legal Name: Test 2022

Pre-Confirmation Number: 55295

Today's Date: 10/17/2022

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.

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:

Legal Name: Test 2022

Pre-Confirmation Number: 55295

Today's Date: 10/17/2022

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

Next

Previous

Select New Establishment

CBER On-Line Main Menu

HCT/P Listing 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 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	☐			
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	☐			

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Function Information Screen

FEI:		Pre-Confirmation Number: 55294								
Legal Name:		Today's Date: 10/14/2022								
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
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Donor Information Screen

FEI:
Legal Name:

Pre-Confirmation Number: 55294
Today's Date: 10/14/2022

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					

Next
 Previous
 Select New Establishment
 CBER On-Line Main Menu

Additional Information to Complete HCT/P Information Listing Screen

FEI:
Legal Name:

Pre-Confirmation Number: 55294
Today's Date: 10/14/2022

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

Next
 Previous
 Select New Establishment
 CBER On-Line Main Menu

Reporting Official Signature Screen

eHCTERS - Reporting Official Signature

Current User:

Date: 10/14/2022

By entering your Reporting Official E-Mail Address and continuing with your submission of this information to FDA/CBER, you are certifying that:

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:

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 1)

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
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Importer(s)

Name and Organization	Address	Phone and Email
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FEI:

FDA information collection OMB Control number: 0910-0543, expiration date: 07/31/2023
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Legal Name: