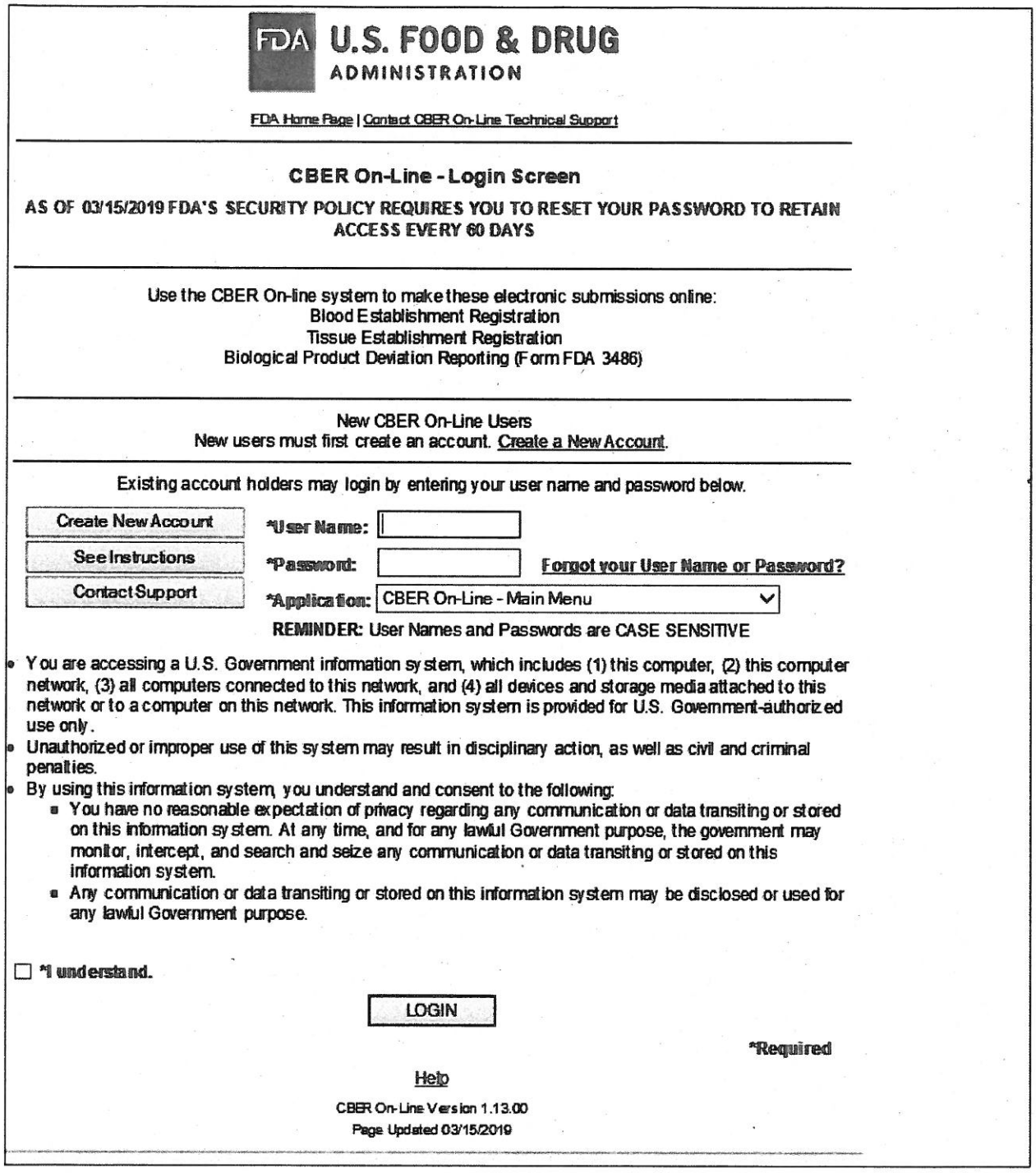
CBER On-Line- Login Screen



FDA U.S. FOOD & DRUG ADMINISTRATION

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.

Create New Account
See Instructions
Contact Support

*User Name:
*Password:
Forgot your User Name or Password?
*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

Help

CBER On-Line Version 1.13.00
Page Updated 03/15/2019

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.

○ **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

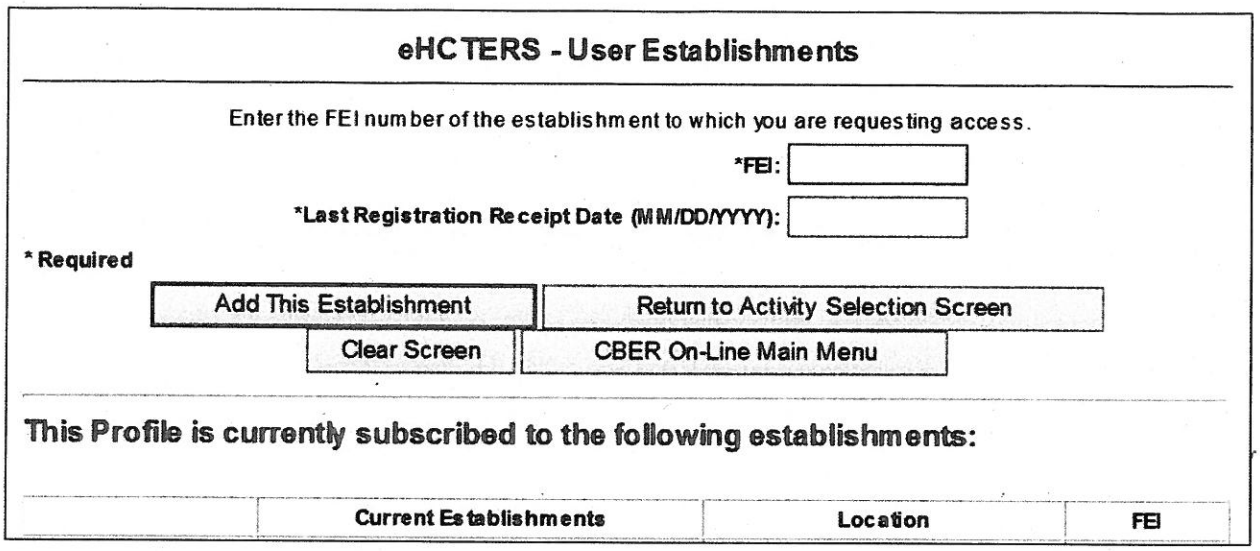
Select from your existing user establishments:

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

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):

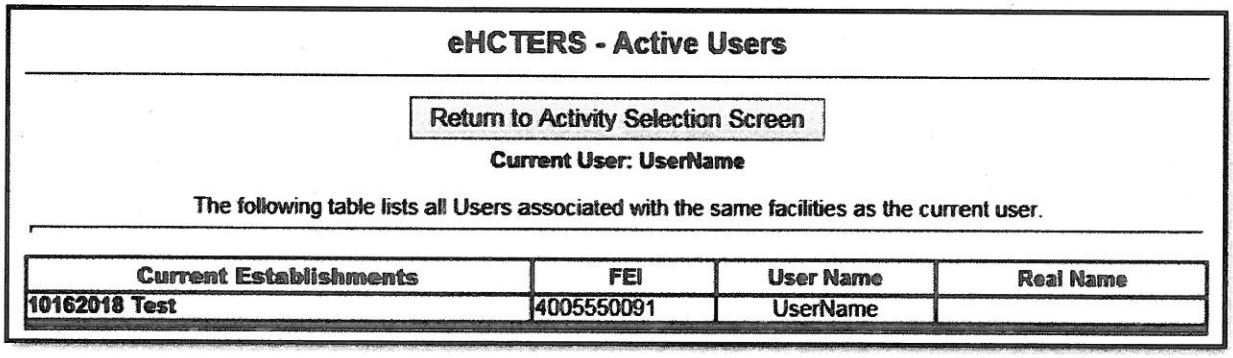
* Required

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

Active Users Screen



eHCTERS - Active Users

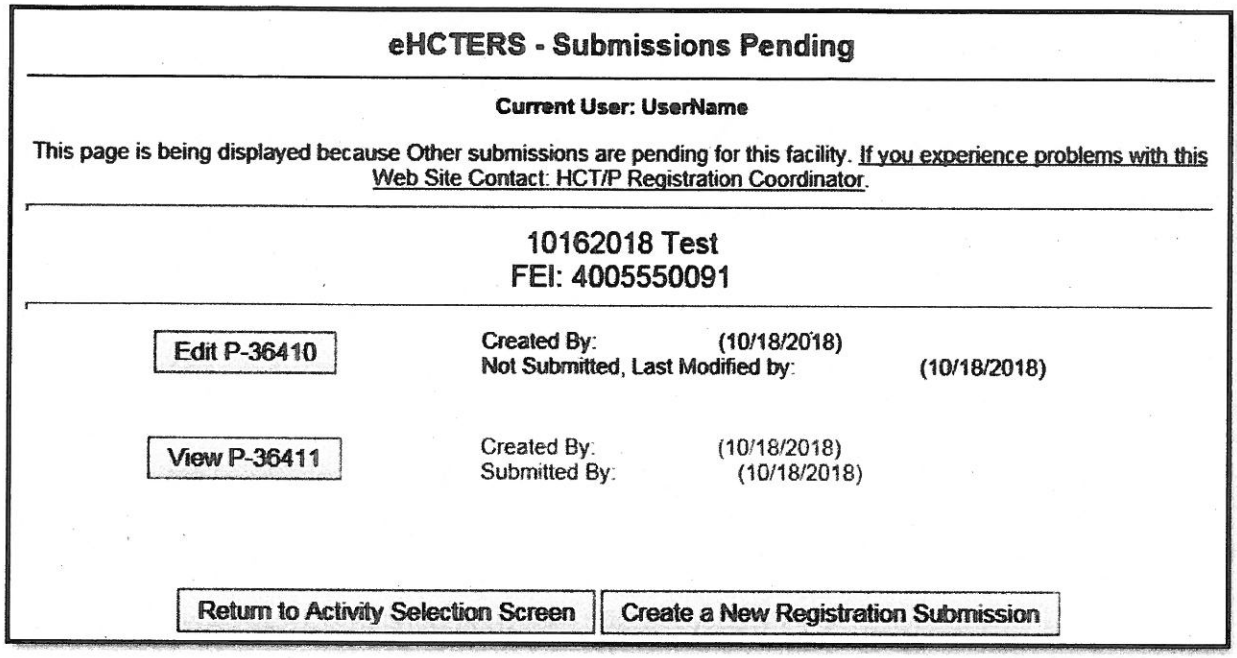
Return to Activity Selection Screen

Current User: UserName

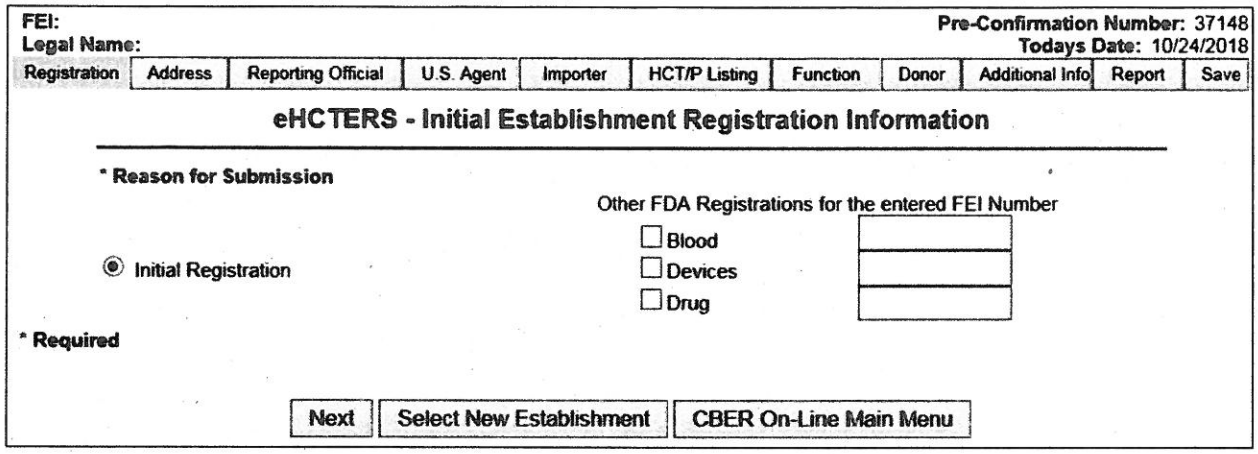
The following table lists all Users associated with the same facilities as the current user.

Current Establishments	FEI	User Name	Real Name
10162018 Test	4005550091	UserName	

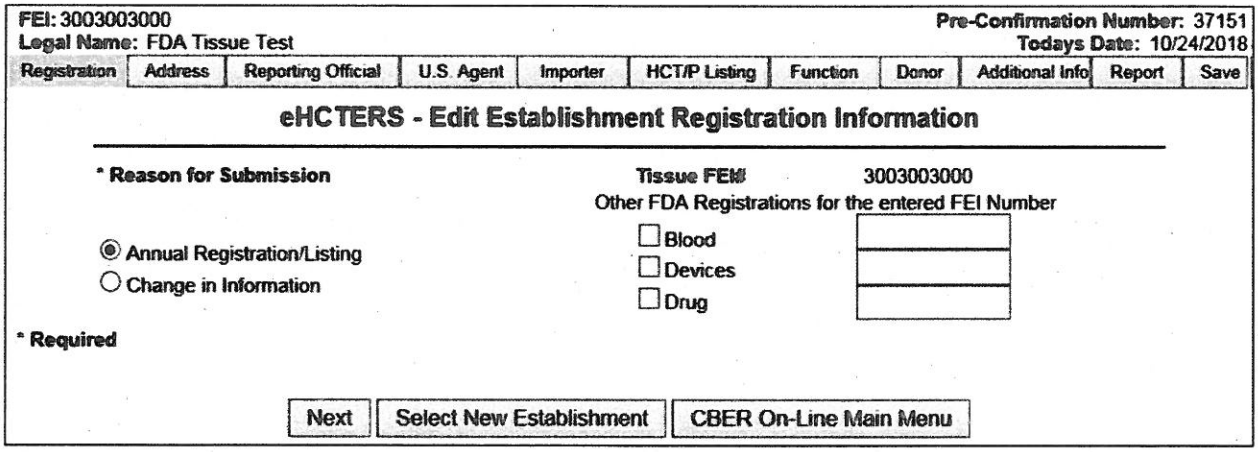
Submissions Pending Screen



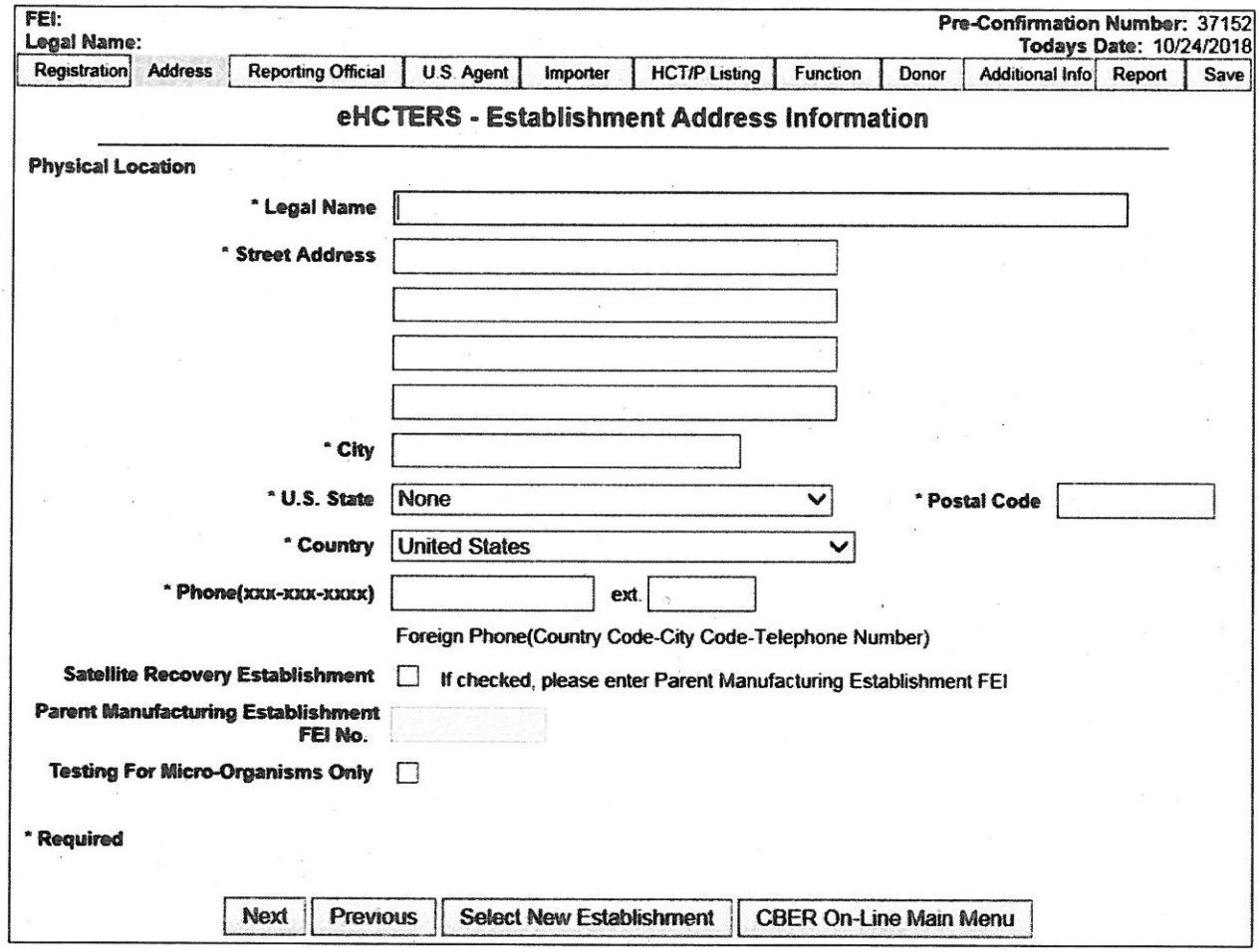
Initial Establishment Registration Information Screen



Edit Establishment Registration Information Screen



Establishment Registration Address Information Screen



FEI:
Legal Name:

Pre-Confirmation Number: 37152
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: None
* Postal Code
* Country: United States
* 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

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

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

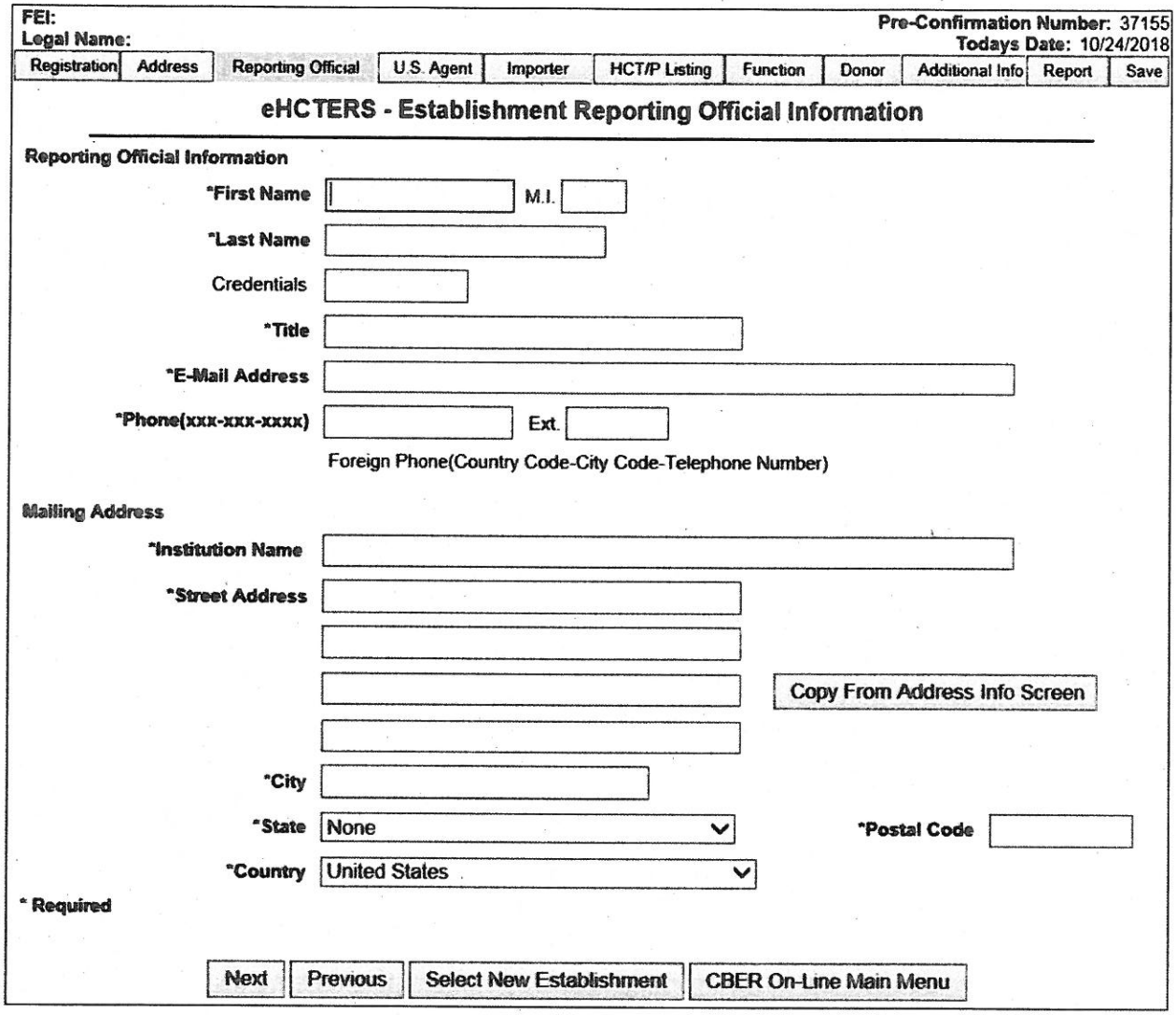
Your establishment may already be registered. Please review the list of possible matches below. You may view detailed information about each establishment by clicking the establishment name.

- 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
FDA Tissue Test	Rockville, MD / 20852	3003003000	Pre-registered

CONTINUE WITH INITIAL REGISTRATION | DISCONTINUE INITIAL REGISTRATION

Establishment Reporting Official Information Screen



Establishment U.S. Agent Information Screen

FEI:
Legal Name:

Pre-Confirmation Number: 37156
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 [ ]

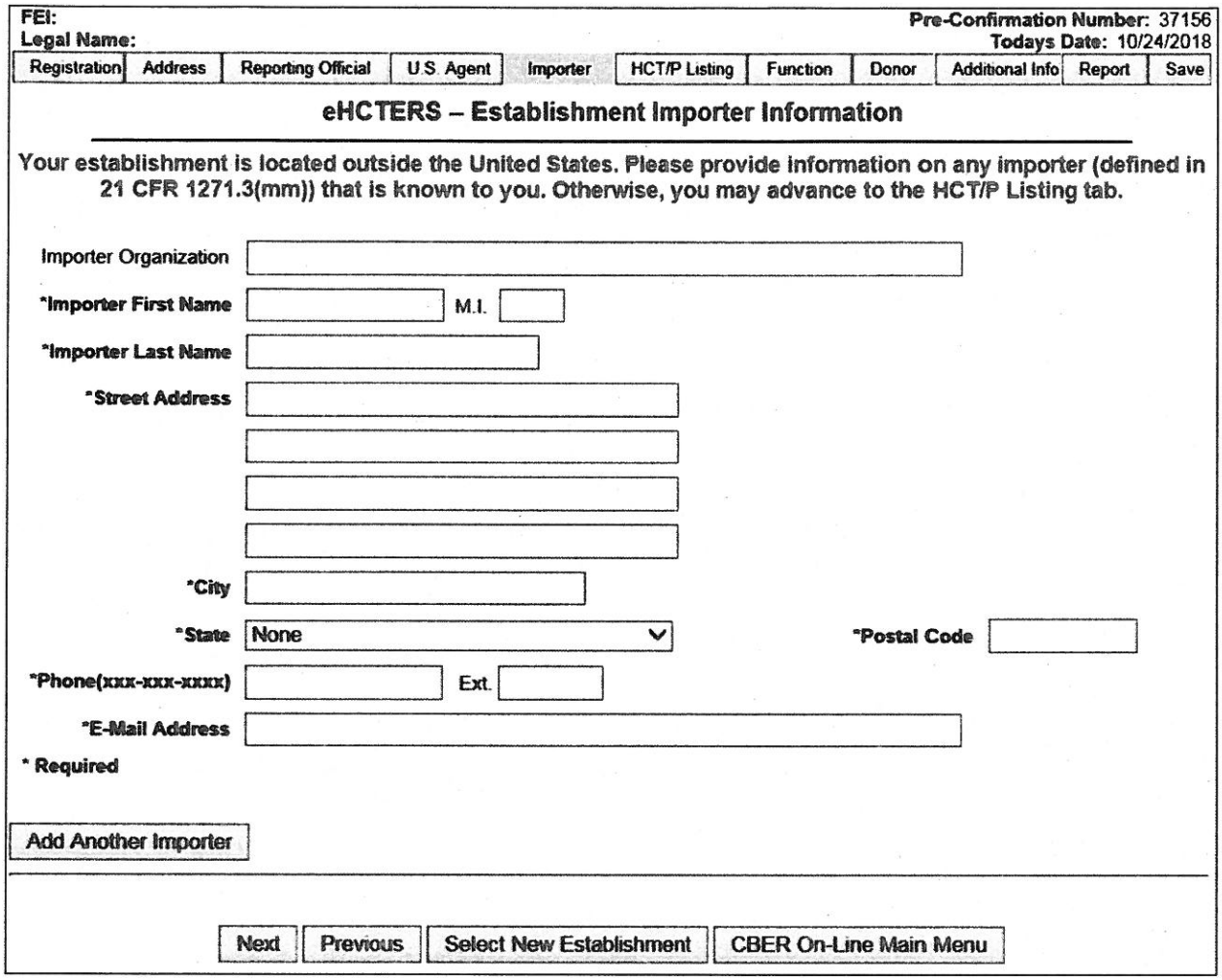
*State None *Postal Code [ ]

* Required

Add Another U.S. Agent

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

Establishment Importer Information Screen



FEI:
Legal Name:

Pre-Confirmation Number: 37156
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 None *Postal Code

*Phone(xxx-xxx-xxxx) Ext.

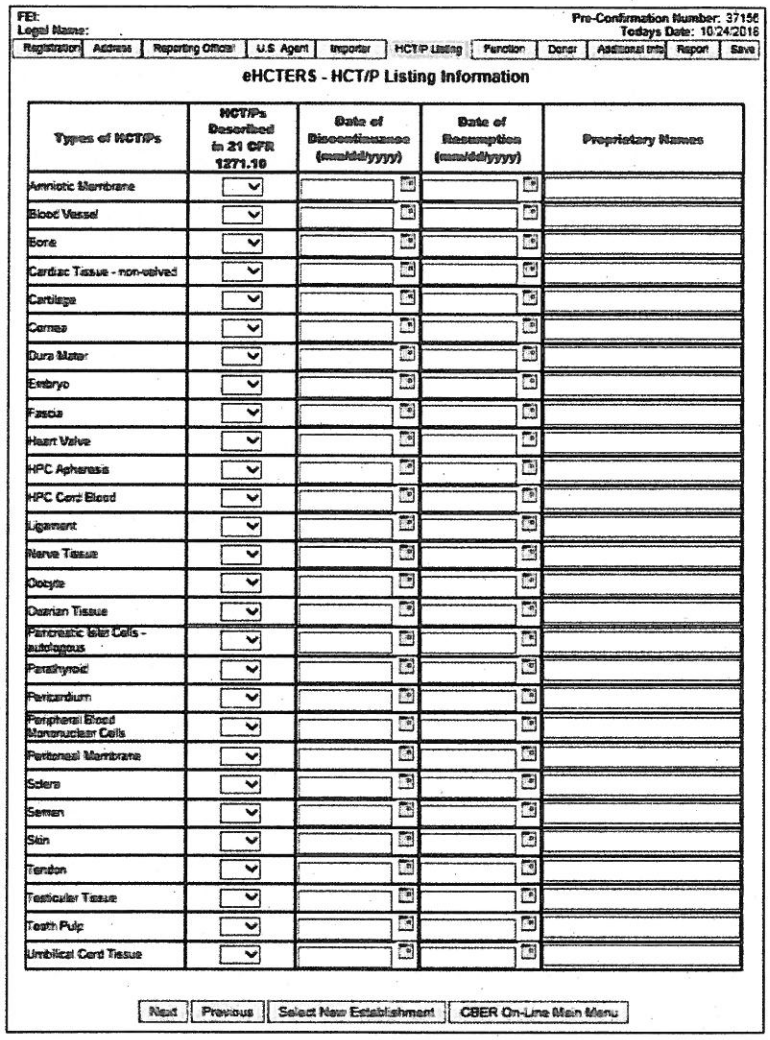
*E-Mail Address

* Required

Add Another Importer

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

HCT/P Listing Information Screen



FEI:
Legal Name:

Pre-Confirmation Number: 37156
Todays Date: 10/24/2016

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				

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

Function Information Screen

FEI:
Legal Name:

Pre-Confirmation Number: 37156
Todays Date: 10/24/2018

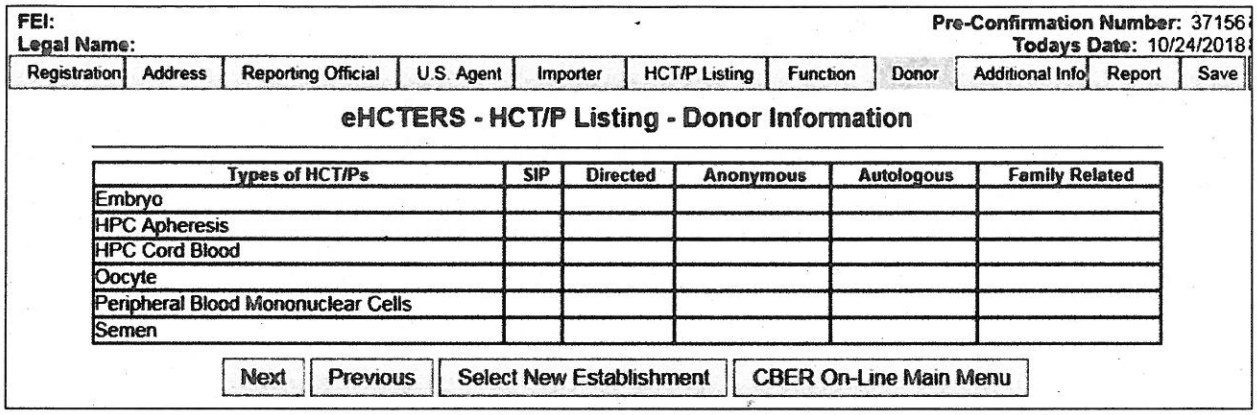
Registration | Address | Reporting Official | U.S. Agent | Importer | HCT/P Listing | Function | Donor | Additional Info | Report | Save

eHCTERS - HCT/P Listing - Function Information

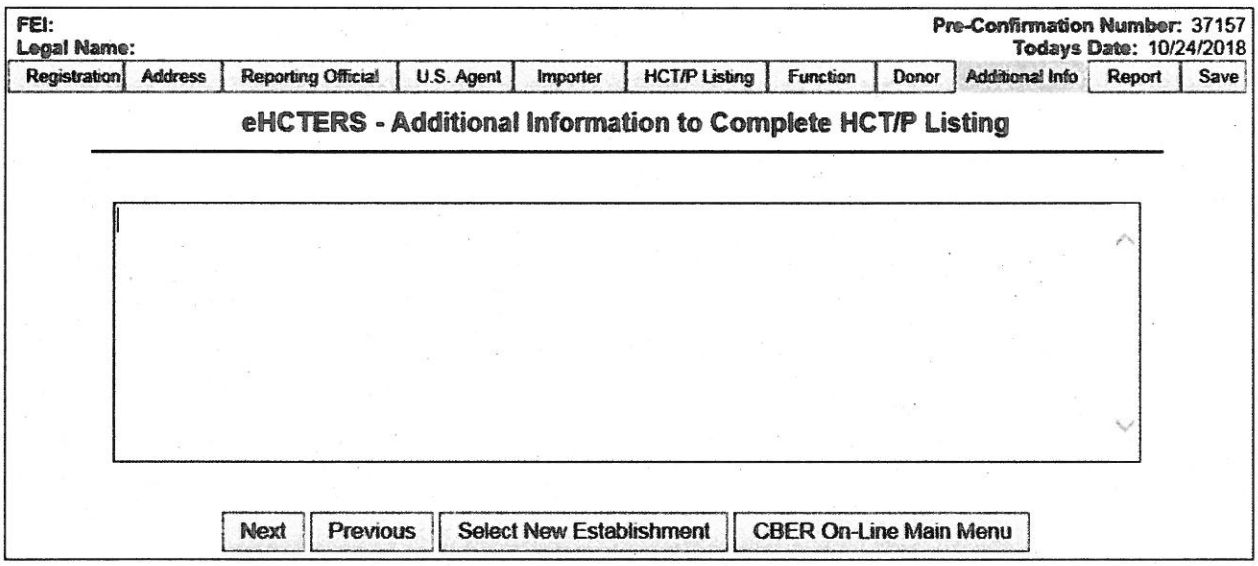
Types of HCT/Ps	Recover	Screen	Donor Testing	Package	Process	Store	Label	Distribute
Amniotic Membrane								
Blood Vessel								
Bone								
Cardiac Tissue - non-valved								
Cartilage								
Cornea								
Dura Mater								
Embryo								
Fascia								
Heart Valve								
HPC Apheresis								
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



Additional Information to Complete HCT/P Information Listing Screen



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:

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: [ ] Continue 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.

Print information submitted for HCT/P establishment registration

Close

Registration Summary Report Provided to the Establishments (Example-Page 1)

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION **ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS DESCRIBED IN 21 CFR 1271.10**	**FEI:**	**Other FDA Registrations:** **Blood:** **Devices:** **Drugs:**	Reason For Last Submission: Annual Registration/Listing Last Annual Registration Year: 2019 Last Registration Receipt Date: 11/21/2018 Summary Report Print Date: 05/21/2019
Legal Name and Location: **Ext.:**	**Reporting Official:**		**Satellite Recovery Establishment:** No **Parent Manufacturing Establishment FEI No.:** **Testing For Micro-Organisms Only:** No Note: FDA acceptance of an establishment registration and HCT/P listing does not constitute a determination that an establishment is in compliance with applicable rules and regulations or that the HCT/P is licensed or approved by FDA (21 CFR 1271.27(b)).

HCT/P(s)	Donor Type(s)	Establishment Functions								Date of Discontinuance	Date of Resumption	Proprietary Name(s)
		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	Autologous, Family Related	X	X	X	X	X	X	X	X			
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												

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