

Blood Establishment Registration



CBER On-Line - Login Screen

Use the CBER On-line system to make these electronic submissions online:
Blood Establishment Registration (Form FDA 2830)
Tissue Establishment Registration (Form FDA 3356)
Biological Product Deviation Reporting (Form FDA 3486)

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

If you need further assistance e-mail us with your account information: [Contact CBER On-Line Technical Support](#)

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:

REMINDER: User Names and Passwords are CASE SENSITIVE

LOGIN

*Required



CBER On-Line - Main Menu

Production Applications

[Biological Product Deviation Reporting
\(eBPDR\)](#)

[Blood Establishment Registration \(eBER\)](#)

[HCT/P Establishment Registration
\(eHCTERS\)](#)

Welcome to the CBER On-Line

[Exit CBER On-Line Application](#)

[Edit Current Account](#)

[Change Password](#)

CBER On-Line Version 1.8.0

Page Updated 12/18/2008

[Contact CBER On-Line Technical Support](#) | [Help](#) | [Release Notes](#) | [Log Out](#)



Blood Establishment Registration - Select Establishment

Last Session Login: 02/09/2018 15:36:40

If your establishment has never registered before:
(Either here online or by completing a FORM FDA 2830)
Select the **Initial Registration** button below.

If you want to edit the list of establishments you have access to or request access to an existing establishment's registration information: Select the **Edit User Establishments Profile** button below.

If you are updating your establishment registration information: Enter either your FDA Establishment Identifier (FEI) or Central File Number (CFN) in the appropriate box below.
If you are returning to complete a form started in a previous session enter the Pre-Confirmation Number below.
Then Select the **Edit This Establishment** button below.

Frequently Asked Questions

*FDA Establishment Identifier (FEI):

OR *Central File Number (CFN):

OR *Pre-Confirmation Number:

*Required

Edit This Establishment

Initial Registration

Clear

Edit User Establishments Profile

View All Active Users

CBER On-Line Main Menu



Blood Establishment Registration - Registration Profile

USER ESTABLISHMENTS

Enter the Registration number [either FEI or CFN] and the most recent Validated Date of the establishment for which you want to request access.

*Registration Type: FEI
 CFN

*Registration Number:

*Validated Date: (mm/dd/yyyy)

* Required

Add This Establishment

Return to Select Establishment page

Clear Screen

Blood Establishment Registration - Status

Facility's Current Production Status: ACTIVE

Please enter the current status of this Blood Establishment Registration. Only an Active Status will allow you to modify Establishment information. Inactive Status will only allow review and submission of the FORM FDA 2830.

***Enter Current Status**

-----Select Status -----
Active - Annual Registration
Active - Change in Information
Inactive Exempt
Inactive Closed
Inactive Temporary

***Required**

Continue

Refresh

ER On-Line Main Menu

FORM FDA 2830 (5/15) Form Approved: OMB No.0910-0052
Expiration Date: May 31, 2018 Previous Editions are Obsolete
eBER v1.14.00
Updated 11/14/2014



Legal Name:

Pre-Confirm Number: 36140

Today's Date: 02/14/2018

| | | | | | | | |
|----------|-----------------|------------|------------|------------|----------|--------|------|
| Location | Report Official | U.S. Agent | Owner Type | Estab Type | Products | Report | Save |
|----------|-----------------|------------|------------|------------|----------|--------|------|

Blood Establishment Registration - Legal Name/Location

License Number Parent Lic. No.

FEI CFN

*Legal Name

*Address

*City

*State *Zip

*Country United States

Phone(xxx-xxx-xxxx) Extension
Foreign(Country-City-Local)

*Required

Other Names used at this Location

**ADD other names used at this location

| | | | | |
|----------|-------|---------|-----------------|------------------------|
| Continue | Clear | Refresh | Change Facility | CBER On-Line Main Menu |
|----------|-------|---------|-----------------|------------------------|



Legal Name:

Pre-Confirm Number: 36140

Today's Date: 02/14/2018

| | | | | | | | |
|----------|-----------------|------------|------------|------------|----------|--------|------|
| Location | Report Official | U.S. Agent | Owner Type | Estab Type | Products | Report | Save |
|----------|-----------------|------------|------------|------------|----------|--------|------|

Blood Establishment Registration - Other Names

*Name

*Reported Date mm/dd/yyyy

*Required

| | |
|---------------|---|
| Add This Name | Return to Establishment Location Form [does not save] |
|---------------|---|

FORM FDA 2830 (5/15) Form Approved: OMB No.0910-0052
Expiration Date: May 31, 2018 Previous Editions are Obsolete
eBER v1.14.00
Updated 06/27/2014



Legal Name:

Pre-Confirm Number: 36140

Today's Date: 02/14/2018

| | | | | | | | |
|----------|-----------------|------------|------------|------------|----------|--------|------|
| Location | Report Official | U.S. Agent | Owner Type | Estab Type | Products | Report | Save |
|----------|-----------------|------------|------------|------------|----------|--------|------|

Blood Establishment Registration - Reporting Official

Organization

***Reporting Official Name**
(First / Middle Initial / Last) / /

In Care Of

***Address**

***City**

***State** ***Zip**

***Country** United States

Phone(XXX-XXX-XXXX) Extension

Foreign Phone (Country-City-Local)

E-Mail

***Required**

| | | | | |
|----------|-------|---------|-----------------|------------------------|
| Continue | Clear | Refresh | Change Facility | CBER On-Line Main Menu |
|----------|-------|---------|-----------------|------------------------|



Legal Name:

Pre-Confirm Number: 36142

Today's Date: 02/14/2018

| | | | | | | | |
|----------|-----------------|-------------|------------|------------|----------|--------|------|
| Location | Report Official | U. S. Agent | Owner Type | Estab Type | Products | Report | Save |
|----------|-----------------|-------------|------------|------------|----------|--------|------|

Blood Establishment Registration - U.S. Agent

Your establishment is located in the United States. You are not required to have a U.S. Agent. We will not save U.S. Agent information for establishments located in the U.S.

Organization

***US Agent Name**
(First / Middle Initial / Last) / /

In Care Of

***Address**

***City**

***State** ***Zip**

Country United States

E-Mail

***Phone(xxx-xxx-xxxx)** Extension

***Required**

| | | | | |
|----------|-------|---------|-----------------|------------------------|
| Continue | Clear | Refresh | Change Facility | CBER On-Line Main Menu |
|----------|-------|---------|-----------------|------------------------|



Legal Name:

Pre-Confirm Number: 36140

Today's Date: 02/14/2018

| | | | | | | | |
|----------|-----------------|------------|------------|------------|----------|--------|------|
| Location | Report Official | U.S. Agent | Owner Type | Estab Type | Products | Report | Save |
|----------|-----------------|------------|------------|------------|----------|--------|------|

Blood Establishment Registration - Owner Type

*Type of Ownership

- Single Proprietorship
- Partnership
- Corporation > Profit Non-Profit
- Cooperative Association
- Federal (non-military)
- U.S. Military
- State
- County/Municipal/Hospital Authority
- Other

*Required

| | | | | |
|----------|-------|---------|-----------------|------------------------|
| Continue | Clear | Refresh | Change Facility | CBER On-Line Main Menu |
|----------|-------|---------|-----------------|------------------------|



Legal Name:

Pre-Confirm Number: 36140

Today's Date: 02/14/2018

| | | | | | | | |
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| Location | Report Official | U.S. Agent | Owner Type | Estab Type | Products | Report | Save |
|----------|-----------------|------------|------------|------------|----------|--------|------|

Blood Establishment Registration - Establishment Type

*Establishment Type

- Community (Non-Hospital) Blood Bank
- Hospital Blood Bank
- Plasmapheresis Center
- Product Testing Lab >> Independent Associated with Community or Hospital Blood Bank
- Hospital Transf. Svc. >> Approved Medicare Not Approved Medicare
- Component Preparation Facility
- Collection Facility
- Distribution Center
- Broker/Warehouse
- Other

*Required

| | | | | |
|----------|-------|---------|-----------------|------------------------|
| Continue | Clear | Refresh | Change Facility | CBER On-Line Main Menu |
|----------|-------|---------|-----------------|------------------------|



Legal Name:

Pre-Confirm Number: 36140

Today's Date: 02/14/2018

| | | | | | | | |
|----------|-----------------|------------|------------|------------|----------|--------|------|
| Location | Report Official | U.S. Agent | Owner Type | Estab Type | Products | Report | Save |
|----------|-----------------|------------|------------|------------|----------|--------|------|

Blood Establishment Registration - Products

| | | | | | |
|--------------------|----------|-------|---------|-----------------|------------------------|
| Add Other Products | Continue | Clear | Refresh | Change Facility | CBER On-Line Main Menu |
|--------------------|----------|-------|---------|-----------------|------------------------|

| Donor Types <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Allogeneic Autologous Directed | COLLECT (1) | MANUAL APHERESIS (2) | AUTOMATED APHERESIS (3) | PREPARE (4) | LEUKOCYTES REDUCED (5) | IRRADIATED (6) | DONOR RETESTED (7) | TEST (8) | STORE AND DISTRIBUTE TO OTHERS (9) |
|---|--------------------------|----------------------------|-------------------------------|--------------------------|------------------------------|--------------------------|--------------------------|--------------------------|---|
| (1) WHOLE BLOOD | <input type="checkbox"/> | | | | <input type="checkbox"/> | <input type="checkbox"/> | | <input type="checkbox"/> | <input type="checkbox"/> |
| (2) RED BLOOD CELLS | | | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | <input type="checkbox"/> | <input type="checkbox"/> |
| (3) RED BLOOD CELLS FROZEN | | | | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| (4) RED BLOOD CELLS DEGLYCEROLIZED | | | | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| (5) RED BLOOD CELLS REJUVENATED | | | | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | <input type="checkbox"/> | <input type="checkbox"/> |
| (6) RED BLOOD CELLS REJUVENATED FROZEN | | | | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| (7) RED BLOOD CELLS REJUVENATED DEGLYCEROLIZED | | | | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| (8) CRYOPRECIPITATED AHF | | | | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| (9) PLATELETS | | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | <input type="checkbox"/> | <input type="checkbox"/> |
| (10) LEUKOCYTES/GRANULOCYTES | | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | <input type="checkbox"/> | | <input type="checkbox"/> | <input type="checkbox"/> |
| (11) PLASMA | | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| (12) PLASMA CRYOPRECIPITATE REDUCED | | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| (13) FRESH FROZEN PLASMA | | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| (14) LIQUID PLASMA | | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | <input type="checkbox"/> | <input type="checkbox"/> |
| (15) THERAPEUTIC EXCHANGE PLASMA | | <input type="checkbox"/> | <input type="checkbox"/> | | | | | <input type="checkbox"/> | <input type="checkbox"/> |
| (16) SOURCE LEUKOCYTES | | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | | | <input type="checkbox"/> | <input type="checkbox"/> |
| (17) SOURCE PLASMA | | <input type="checkbox"/> | <input type="checkbox"/> | | | | | <input type="checkbox"/> | <input type="checkbox"/> |
| (18) RECOVERED PLASMA | | | | <input type="checkbox"/> | | | | <input type="checkbox"/> | <input type="checkbox"/> |
| (19) BLOOD PRODUCTS FOR DIAGNOSTIC USE | <input type="checkbox"/> | | | <input type="checkbox"/> | | | | <input type="checkbox"/> | <input type="checkbox"/> |
| (20) BLOOD BANK REAGENTS | | | | <input type="checkbox"/> | | | | <input type="checkbox"/> | <input type="checkbox"/> |



Legal Name:

Pre-Confirm Number: **36140**

Today's Date: **02/14/2018**

| | | | | | | | |
|----------|-----------------|------------|------------|------------|----------|--------|------|
| Location | Report Official | U.S. Agent | Owner Type | Estab Type | Products | Report | Save |
|----------|-----------------|------------|------------|------------|----------|--------|------|

Blood Establishment Registration - Other Products

Albumin (Human)

- Anti-HBsAg
- Anti-HIV-1
- Antihem. Factor (Human)
- Antihem. Factor (Recombinant)
- Anti-Inhibit. Coagulant Complex
- Blood Components (Recovered)
- Blood Components for Research
- Coag. Factor VIIa (Recombinant)
- Factor IX Complex
- Fibrin Sealant
- Fraction II
- Hep. B Imm. Globulin (Human)
- HCV Encoded Antigen
- HIV-1 or -2 or -1/2
- HTLV-I or -II or III
- Imm. Globulin (Human)
- Imm. Globulin IV (Human)
- Plasma Protein Fraction
- Platelets Washed
- Pooled Plasma SD
- Red Blood Cells Washed
- Rho(D) Imm. Globulin (Human)
- Rho(D) Imm. Globulin IV (Human)
- Tetanus Imm. Globulin (Human)
- V. Zoster Imm. Globulin (Human)
- Vaccinia Imm. Globulin (Human)
- Not Listed

| COLLECT (1) | MANUAL APHERESIS (2) | AUTOMATED APHERESIS (3) | PREPARE (4) | LEUKOCYTES REDUCED (5) | IRRADIATED (6) | DONOR RETESTED (7) | TEST (8) | STORE AND DISTRIBUTE TO OTHERS (9) |
|--------------------------|----------------------------|-------------------------------|--------------------------|------------------------------|--------------------------|--------------------------|--------------------------|---|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

| | |
|------------|--|
| Set Screen | Clear this form and Return to Product form |
|------------|--|

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 Updated 05/27/2014

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