Blood Establishment Registration





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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	*User Name:	
See Instructions	*Password: Forgot your User Name or Pass	sword?
Contact Support	*Application: CBER On-Line - Main Menu	
	REMINDER: User Names and Passwords are CASE SENSITIVE	
	LOGIN	

*Required





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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

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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.

*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

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





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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.

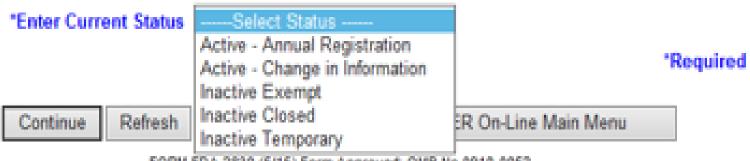
*Regis	tration Type: FEI CFN
*Registrat	ion Number:
*Val	lidated Date: (mm/dd/yyyy)
	* Required
Add This Establishment	Return to Select Establishment page Clear Screen

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

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.



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





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Legal N Pre-Con	ame: firm Numbe	er: 3614	0				Toda	ays Date: 02	2/14/2018		
Locatio	n Report	Official	U.S. A	Agent	Owner Type	Estab Type	Products	Report	Save		
	Blood Establishment Registration - Legal Name/Location										
	Lic	ense Nui	mber			Parent Lic. N	No.]		
			FEI		CFN						
	*L	egal Na	ıme								
		*Addı	ress								
		*	City								
		*S	tate	✓ *Zip							
		*Cou	ntry Uni	United States							
	Phor Foreign(Cou	ne(xxx-xxx- untry-City-L			Exte	ension					
			,					*Red	quired		
Other N	ames used	at this L	ocation								
			**/	ADD oth	ner names used	at this location	1				
	Continue	Clear	Refresh	(Change Facility	CBE	R On-Line Ma	in Menu			





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		FDA HOIRE Page	COMITACT EDEK TEC	annical Support Lo	iq Out		
Legal Name	e: n Number: 36140				Toda	ays Date: 0	2/14/2018
Location	ocation Report Official U.S. Agent Owner Type Estab Type					Report	Save
	Bloo	d Establish	ment Regist	ration - Othe	er Names		
	*Report	*Name 02/14	1/2018 mm	/dd/yyyy			
						*Re	equired
Add 1	This Name	Retur	n to Establishm	nent Location Fo	orm [does not	save]	
				-			

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FDA / Center for Biologics Evaluation and Research





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Legal Nam Pre-Confirn	e: n Number: 36140				Toda	ays Date: ()2/14/2018
Location	Report Official	U.S. Agent	Owner Type	Estab Type	Products	Report	Save
	Blood B	Establishme	ent Registra	tion - Repor	ting Officia	I	
	Organizat	ion					
	oorting Official Na irst / Middle Initial / L			/			
	In Care	Of					
	*Addre	ess					
	*C	ity					
	*Sta	ate			∨ *Zip		
	*Coun	try United Sta	ates		~		
	Phone(xxx-xxx-xx	ox)	Ext	ension			
Foreign F	hone (Country-City-Lo	cal)					
	E-M	Mail					
						*Re	quired
Co	ontinue Clear	Refresh (Change Facility	CBE	R On-Line Ma	in Menu	





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egal Na Pre-Conf		er: 36142	2			Toda	ays Date:	02/14/2018					
Location	Report	Official	U.S. Age	ent Owner Type	Estab Type	Products	Report	Save					
	Blood Establishment Registration - U.S. Agent our 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												
Your est								t. We will					
	Org	anization											
(Firs				/	/								
	Ir	Care Of											
	*	Address											
						_							
		*City											
		*State			~	*Zip							
		Country	United State	es									
		E-Mail											
*Pho	ne(xxx-xx	x-xxxx)		Extension									
							*Re	equired					
	Continue	Clear	Refresh	Change Facility	CBE	R On-Line Mai	n Menu						





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Legal Nam Pre-Confirn	e: n Number: 36140				Toda	ays Date:	02/14/2018
Location	Report Official	U.S. Agent	Owner Type	Estab Type	Products	Report	Save
	Bloo	d Establish	ment Regis	tration - Owi	ner Type		
*Type	of Ownership						
(Single Proprieto 	rship					
(Partnership 						
(Ocrporation >	O Profit	Non-Profit				
(Cooperative Ass	ociation					
(Federal (non-mi	litary)					
(U.S. Military						
(○ State						
(County/Municipa	I/Hospital Autho	rity				
(Other Not Liste	ed 🗸					
	-					*R	equired
Со	ontinue Clear	Refresh (Change Facility	CBE	R On-Line Ma	in Menu	





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ocation	Report Official	U.S. Agent	Owner Type	Estab Type	Products	Report	Save
	Blood E	stablishme	ent Registrati	on - Establis	shment Typ	е	
*Es	tablishment Type						
	Community	(Non-Hospital) Blood Bank				
	☐ Hospital Blo	od Bank					
	Plasmapher	resis Center					
	☐ Product Tes	ting Lab >>	O Independent		sociated with 0 Hospital Blood	-	
	Hospital Tra	nsf. Svc. >>	O Approved Med	dicare O No	ot Approved Me	dicare	
	Component	Preparation F	acility				
	☐ Collection F	acility					
	Distribution	Center					
	☐ Broker/Ware	house					
	Other Selec	ct Option	<u> </u>	•			
						 *Re	quired





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 Legal Name:

 Pre-Confirm Number:
 36140
 Todays Date:
 02/14/2018

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

Blood Establishment Registration - Products

Blood Establishment Registration - Products											
Add Other Products Co	ntinue	Clear	Refresh	Char	nge Facility	CBER C	n-Line M	ain N	1enu		
Donor Types 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											
(2) RED BLOOD CELLS											
(3) RED BLOOD CELLS FROZEN											
(4) RED BLOOD CELLS DEGLYCEROLIZED											
(5) RED BLOOD CELLS REJUVENATED											
(6) RED BLOOD CELLS REJUVENATED FROZEN											
(7) RED BLOOD CELLS REJUVENATED DEGLYCEROLIZED											
(8) CRYOPRECIPITATED AHF											
(9) PLATELETS											
(10) LEUKOCYTES/GRANULOCYTES											
(11) PLASMA											
(12) PLASMA CRYOPRECIPITATE REDUCED											
(13) FRESH FROZEN PLASMA											
(14) LIQUID PLASMA											
(15) THERAPEUTIC EXCHANGE PLASMA											
(16) SOURCE LEUKOCYTES											
(17) SOURCE PLASMA											
(18) RECOVERED PLASMA											
(19) BLOOD PRODUCTS FOR DIAGNOSTIC USE											
(20) BLOOD BANK REAGENTS											



Not Listed

U.S. Food and Drug Administration 🗳



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Legal Name Pre-Confirm	e: n Number: 36140				Toda	ays Date: 0	2/14/201
Location	Report Official	U.S. Agent	Owner Type	Estab Type	Products	Report	Save

Albumin (Human)	Establi	shment	Registrat	tion - O	ther Prod	ucts			_
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 I/II Imm. Globulin (Human) Imm. Globulin IV (Human) Plasma Protein Fraction Platelets Washed	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)
	xpiration D	2830 (5/15) ate: May 31, e Upd	Form Approve 2018 Previous BER v1.14.00 ated 06/27/20 th filling out 9	d: OMB No s Editions of 14 tis_form R		FAQ Log Ou		1	
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)	FDA/C	Center for Bio	ologics Evaluat	ion and Re	ssearch				