

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
BLOOD ESTABLISHMENT REGISTRATION AND PRODUCT LISTING

PLEASE READ INSTRUCTIONS CAREFULLY. Be sure to indicate any changes in your legal name or actual location in item 4, and any changes in your mailing address in item 6. Print all entries and make all corrections in red ink, if possible. Enter your phone number in item 8.3 and the phone number of your actual location in item 4.1. Sign the form and return to FDA. After validation, you will receive your Official Registration for the ensuing year.

ENTER ALL CHANGES IN RED INK AND CIRCLE.

4. LEGAL NAME AND LOCATION (Include legal name, number and street, city, state, country, and post office code)

Central Texas Regional Blood and Tissue Center
4300 North Lamar Boulevard
Austin, TX 78756-3421

4.1 PHONE 512-206-1266

5. OTHER NAMES USED AT THIS LOCATION (Include trade name, doing-business-as, previous names, and other firms co-located. If applicable, include registration number.)

Austin Donor Center
The Blood & Tissue Center of Central Texas

6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code)

Central Texas Regional Blood and Tissue Center
ATTN: Wendy R. Bailey, QA Compliance Manager
4300 N. Lamar Boulevard
Austin, TX 78765-4679

7. U.S. AGENT (Include name, institution name if applicable, number and street, city, state, and zip code)

7.1 E-MAIL ADDRESS
7.2 PHONE

8. REPORTING OFFICIAL'S SIGNATURE

8.1 TYPED NAME Wendy R. Bailey, QA Compliance Manager
8.2 E-MAIL ADDRESS wbailey@ctcms.com
8.3 PHONE 512-206-1134 8.4 DATE

1. REGISTRATION NUMBER
FEI: 1671794
CFN: 1671794
2. U.S. LICENSE NUMBER
244

3. REASON FOR SUBMISSION
1. ANNUAL REGISTRATION
2. INITIAL REGISTRATION
3. CHANGE IN INFORMATION



FOR FDA USE ONLY

This form is authorized by Sections 510(b), (i) and 704 of the Federal Food, Drug, and Cosmetic Act (Title 21, United States Code 360(b), (i) and 374). Failure to report this information is a violation of Section 301(f) and (j) of the Act (Title 21, United States Code 331(f) and (j)) and can result in a fine of up to \$1,000 or imprisonment up to one year or both, pursuant to Section 303(a) of the Act (Title 21, United States Code 333(a)).

9. TYPE OF OWNERSHIP

- 1. SINGLE PROPRIETORSHIP
- 2. PARTNERSHIP
- 3. CORPORATION profit non-profit
- 4. COOPERATIVE ASSOCIATION
- 5. FEDERAL (non-military)
- 6. U.S. MILITARY
- 7. STATE
- 8. COUNTY/MUNICIPAL/HOSPITAL AUTHORITY
- 9. OTHER (Specify):

10. TYPE ESTABLISHMENT (Check all boxes that describe routine or autologous operations.)

- 1. COMMUNITY (NON-HOSPITAL) BLOOD BANK
- 2. HOSPITAL BLOOD BANK
- 3. PLASMAPHERESIS CENTER
- 4. PRODUCT TESTING LABORATORY
- 5. INDEPENDENT ASSOCIATED W/ COMMUNITY or HOSPITAL BLOOD BANK
- 6. HOSPITAL TRANSFUSION SERVICE APPROVED FOR MEDICARE REIMBURSEMENT
- 7. COMPONENT PREPARATION FACILITY
- 8. COLLECTION FACILITY DISTRIBUTION CENTER
- 9. BROKER/WAREHOUSE
- 10. OTHER (Specify):

11. PRODUCTS	ALLOGENIC	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)								
													WHOLE BLOOD	RED BLOOD CELLS (RBC)	RBC FROZEN	RBC DEGLYCEROLIZED	RBC REJUVENATED	RBC REJUVENATED FROZEN	RBC REJUVENATED DEGLYCEROLIZED	CRYOPRECIPITATED AHF
WHOLE BLOOD				X					X			X								
RED BLOOD CELLS (RBC)	X	X	X			X	X	X	X		X	X								
RBC FROZEN							X	X			X	X								
RBC DEGLYCEROLIZED							X	X			X	X								
RBC REJUVENATED																				
RBC REJUVENATED FROZEN																				
RBC REJUVENATED DEGLYCEROLIZED																				
CRYOPRECIPITATED AHF												X								
PLATELETS						X			X		X	X								
LEUKOCYTES/GRANULOCYTES												X								
PLASMA												X								
PLASMA CRYOPRECIPITATE REDUCED							X	X				X								
FRESH FROZEN PLASMA							X	X				X								
LIQUID PLASMA												X								
THERAPEUTIC EXCHANGE PLASMA												X								
SOURCE LEUKOCYTES												X								
SOURCE PLASMA								X				X								
RECOVERED PLASMA												X								
BLOOD PRODUCTS FOR DIAGNOSTIC USE												X								
BLOOD BANK REAGENTS												X								
OTHER												X								