

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION**

BLOOD ESTABLISHMENT REGISTRATION AND PRODUCT LISTING

1. REGISTRATION NUMBER
FEI: 1671794
CFN: 1671794

2. U.S. LICENSE NUMBER
244

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

FOR FDA USE ONLY

DISTRICT OFFICE: Dallas
VALIDATED BY FDA: 21-DEC-2016
PRINTED BY FDA: 18-JAN-2017

This form is authorized by Sections 510(b), (j) and 704 of the Federal Food, Drug, and Cosmetic Act (Title 21, United States Code 360(b), (j) and 374). Failure to report this information is a violation of Section 301(f) and (p) of the Act (Title 21, United States Code 331(f) and (p)) 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

SINGLE PROPRIETORSHIP
 PARTNERSHIP
 CORPORATION profit non-profit
 COOPERATIVE ASSOCIATION
 FEDERAL (non-military)
 U.S. MILITARY
 STATE
 COUNTY/MUNICIPAL/HOSPITAL AUTHORITY
 OTHER (Specify):

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

COMMUNITY (NON-HOSPITAL) BLOOD BANK
 HOSPITAL BLOOD BANK
 PLASMAPHERESIS CENTER
 PRODUCT TESTING LABORATORY
 a. INDEPENDENT
 ASSOCIATED W/ COMMUNITY or HOSPITAL BLOOD BANK
 b. HOSPITAL TRANSFUSION SERVICE
 APPROVED FOR MEDICARE REIMBURSEMENT
 NOT APPROVED FOR MEDICARE REIMBURSEMENT
 COMPONENT PREPARATION FACILITY
 COLLECTION FACILITY
 DISTRIBUTION CENTER
 BROKER/WAREHOUSE
 OTHER (Specify):

U.S. LICENSE NUMBER OF PARENT FIRM

11. PRODUCTS

ALLOGENEIC	AUTOLOGOUS	DIRECTED	COLLECT	MANUAL APHERESIS	AUTOMATED APHERESIS	PREPARE	LEUKOCYTES REDUCED	IRRADIATED	DONOR RETESTED	TEST	STORE and DISTRIBUTE to OTHERS
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)
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4.1 PHONE 512-206-1266

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

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

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 78756-3421

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
 Wendy R. Bailey 01-18-17

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