

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

**BLOOD ESTABLISHMENT REGISTRATION AND PRODUCT LISTING**

**1. REGISTRATION NUMBER**  
FEI: 3004509482  
CFN:  
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), (l) and 704 of the Federal Food, Drug, and Cosmetic Act (Title 21, United States Code 360(b), (l) 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  
 B.  INDEPENDENT  
 ASSOCIATED W/ COMMUNITY or HOSPITAL BLOOD BANK  
 HOSPITAL TRANSFUSION SERVICE  
 B.  APPROVED FOR MEDICARE REIMBURSEMENT  
 NOT APPROVED FOR MEDICARE REIMBURSEMENT  
 COMPONENT PREPARATION FACILITY  
 COLLECTION FACILITY  
 DISTRIBUTION CENTER  
 BROKER/WAREHOUSE  
 OTHER (Specify): 244 U.S. LICENSE NUMBER OF PARENT FIRM

**11. PRODUCTS**

ALLOGENIC	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)
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	1	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			2	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			3	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			4	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			5	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			6	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			7	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			8	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			9	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			10	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			11	<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	<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	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			14	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			15	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			16	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			17	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			18	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			19	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			20	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			21	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**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 North Lamar Boulevard  
 Austin, TX 78756

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

**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