

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

1. REGISTRATION NUMBER
FEI: 3011873059
CFN:
2. U.S. LICENSE NUMBER
2069

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



FOR FDA USE ONLY
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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 (g) of the Act (Title 21, United States Code 331(f) and (g)) 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)).

DISTRICT OFFICE: Dallas
VALIDATED BY FDA: 22-FEB-2017
PRINTED BY FDA: 22-FEB-2017

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)

We Are Blood
3100 West Slaughter Lane
Suite A-106
Austin, TX 78748

4.1. PHONE

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.)
We Are Blood

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

We Are Blood
ATTN: Wendy Bailey
4300 North Lamar Blvd.
Austin, TX 78756

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 Bailey 03-22-17

8.1 TYPED NAME
8.2 E-MAIL ADDRESS
8.3 PHONE

8.4 DATE

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
 - a. INDEPENDENT
 - b. ASSOCIATED w/ COMMUNITY or HOSPITAL BLOOD BANK
- 5. HOSPITAL TRANSFUSION SERVICE
 - a. APPROVED FOR MEDICARE REIMBURSEMENT
 - b. NOT APPROVED FOR MEDICARE REIMBURSEMENT
- 6. COMPONENT PREPARATION FACILITY
- 7. COLLECTION FACILITY
- 8. DISTRIBUTION CENTER
- 9. BROKERWAREHOUSE
- 10. OTHER (Specify):

2069
U.S. LICENSE NUMBER OF PARENT FIRM

11. PRODUCTS

PRODUCT	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 USE BY OTHERS (9)
WHOLE BLOOD	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>								
RED BLOOD CELLS (RBC)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>				
RBC FROZEN												
RBC DEGLYCEROLIZED												
RBC RELUVENATED												
RBC RELUVENATED FROZEN												
RBC RELUVENATED DEGLYCEROLIZED												
CRYOPRECIPITATED AHF												
PLATELETS						<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>				
LEUKOCYTES/GRANULOCYTES												
PLASMA												
PLASMA CRYOPRECIPITATE REDUCED												
FRESH FROZEN PLASMA							<input checked="" type="checkbox"/>					
LIQUID PLASMA												
THERAPEUTIC EXCHANGE PLASMA												
SOURCE LEUKOCYTES												
SOURCE PLASMA												
RECOVERED PLASMA												
BLOOD PRODUCTS FOR DIAGNOSTIC USE												
BLOOD BANK REAGENTS												
OTHER												