

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

1. REGISTRATION NUMBER

FEI: 3002133806

CFN: 1676569

2. U.S. LICENSE NUMBER

639

3. REASON FOR SUBMISSION

- 1 ANNUAL REGISTRATION
- 2 INITIAL REGISTRATION
- 3 CHANGE IN INFORMATION

FOR FDA USE ONLY



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.

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 33.3(a)).

DISTRICT OFFICE: Dallas
VALIDATED BY FDA: 19-DEC-2017
PRINTED BY FDA: 08-JAN-2018

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)

Gulf Coast Regional Blood Center
1400 La Concha Lane
Houston, TX 77054-1802

4.1 PHONE 713-790-1200

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.)

Headquarters
The Blood Center

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

Gulf Coast Regional Blood Center
ATTN: Brian G. Gannon
1400 La Concha Lane
Houston, TX 77054-1802

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 *Brian Gannon 1-15-18*
Brian G. Gannon

8.2 E-MAIL ADDRESS bgannon@giveblood.org

8.3 PHONE 713-791-6303

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

U.S. LICENSE NUMBER OF PARENT FIRM _____

11. PRODUCTS

	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)
WHOLE BLOOD	1	<input checked="" type="checkbox"/>			<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
RED BLOOD CELLS (RBC)	2		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
RBC FROZEN	3			<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
RBC DEGLYCEROLIZED	4			<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
RBC REJUVENATED	5								
RBC REJUVENATED FROZEN	6								
RBC REJUVENATED DEGLYCEROLIZED	7								
CRYOPRECIPITATED AHF	8			<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
PLATELETS	9		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
LEUKOCYTES/GRANULOCYTES	10								
PLASMA	11								
PLASMA CRYOPRECIPITATE REDUCED	12			<input checked="" type="checkbox"/>				<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
FRESH FROZEN PLASMA	13		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
LIQUID PLASMA	14			<input checked="" type="checkbox"/>				<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
THERAPEUTIC EXCHANGE PLASMA	15								
SOURCE LEUKOCYTES	16			<input checked="" type="checkbox"/>				<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
SOURCE PLASMA	17		<input checked="" type="checkbox"/>					<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
RECOVERED PLASMA	18			<input checked="" type="checkbox"/>				<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
BLOOD PRODUCTS FOR DIAGNOSTIC USE	19	<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>				<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
BLOOD BANK REAGENTS	20								
OTHER Pooled Cryoprecipitated AHF	21			<input checked="" type="checkbox"/>				<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Pooled Platelets				<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>			<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>