


DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION BLOOD ESTABLISHMENT REGISTRATION AND PRODUCT LISTING	1. REGISTRATION NUMBER FEI: 1046616 CFN: 1046616 2. U.S. LICENSE NUMBER 881	3. REASON FOR SUBMISSION .1 <input checked="" type="checkbox"/> ANNUAL REGISTRATION .2 <input type="checkbox"/> INITIAL REGISTRATION .3 <input type="checkbox"/> CHANGE IN INFORMATION	FOR FDA USE ONLY  DISTRICT OFFICE: Atlanta VALIDATED BY FDA: 21-DEC-2016 PRINTED BY FDA: 18-JAN-2017
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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 333(a)).

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)

Walter L. Shepard Community Blood Center, Inc.
 1533 Wrightsboro Road
 Augusta, GA 30904-4098

4.1 PHONE 706-737-4551

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 _____

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.)

Shepard Community Blood Center

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

Walter L. Shepard Community Blood Center, Inc.
 ATTN: Kevin J. Belanger
 1533 Wrightsboro Road
 Augusta, GA 30904-4098

11. PRODUCTS	COLLECT	MANUAL APHERESIS	AUTOMATED APHERESIS	PREPARE	LEUKOCYTES REDUCED	IRRADIATED	DONOR RETESTED	TEST	STORE and DISTRIBUTE to OTHERS		
										ALLOGENEIC	AUTOLOGOUS
WHOLE BLOOD	1	X						X	X		
RED BLOOD CELLS (RBC)	2		X	X	X			X	X		
RBC FROZEN	3										
RBC DEGLYCEROLIZED	4										
RBC REJUVENATED	5										
RBC REJUVENATED FROZEN	6										
RBC REJUVENATED DEGLYCEROLIZED	7										
CRYOPRECIPITATED AHF	8			X				X	X		
PLATELETS	9		X	X				X	X		
LEUKOCYTES/GRANULOCYTES	10										
PLASMA	11										
PLASMA CRYOPRECIPITATE REDUCED	12										
FRESH FROZEN PLASMA	13		X	X				X	X		
LIQUID PLASMA	14			X							
THERAPEUTIC EXCHANGE PLASMA	15										
SOURCE LEUKOCYTES	16										
SOURCE PLASMA	17										
RECOVERED PLASMA	18			X				X	X		
BLOOD PRODUCTS FOR DIAGNOSTIC USE	19										
BLOOD BANK REAGENTS	20										
OTHER	21										

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

Kevin J. Belanger
 1533 Wrightsboro Road
 Augusta, GA 30904-4098

7.1 E-MAIL ADDRESS
 7.2 PHONE

8. REPORTING OFFICIAL'S SIGNATURE

Kevin J. Belanger

8.1 TYPED NAME Kevin J. Belanger
 8.2 E-MAIL ADDRESS kbelanger@shepeardblood.org
 8.3 PHONE 706-737-4551 8.4 DATE 26 Jan 2017