


DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION BLOOD ESTABLISHMENT REGISTRATION AND PRODUCT LISTING	1. REGISTRATION NUMBER FEI: 3010133520 CFN: 2. U.S. LICENSE NUMBER 274	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 
---	--	--	---

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: New Jersey
 VALIDATED BY FDA: 02-DEC-2016
 PRINTED BY FDA: 19-DEC-2016

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)

Bergen Community Regional Blood Center
 Bergen Medical Center
 1 West Ridgewood Avenue, Suite 208
 Paramus, NJ 07652

4.1 PHONE 201-444-3900

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.)

CBS Lincoln Park Donor Center
 Community Blood Services

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

Blood Systems, Inc.
 ATTN: Gina Ramirez, Regulatory Manager
 6210 East Oak Street
 P.O. Box 1867
 Scottsdale, AZ 85252-1867

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 Gina Ramirez, Regulatory Manager
 8.2 E-MAIL ADDRESS gramirez@bloodsystems.org
 8.3 PHONE 303-363-2221 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 } 274
 U.S. LICENSE NUMBER OF PARENT FIRM
- .8 DISTRIBUTION CENTER
- .9 BROKER/WAREHOUSE
- .10 OTHER (Specify) : _____

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	X							
RED BLOOD CELLS (RBC)	2		X						
RBC FROZEN	3								
RBC DEGLYCEROLIZED	4								
RBC REJUVENATED	5								
RBC REJUVENATED FROZEN	6								
RBC REJUVENATED DEGLYCEROLIZED	7								
CRYOPRECIPITATED AHF	8								
PLATELETS	9		X		X				
LEUKOCYTES/GRANULOCYTES	10								
PLASMA	11		X						
PLASMA CRYOPRECIPITATE REDUCED	12								
FRESH FROZEN PLASMA	13		X						
LIQUID PLASMA	14								
THERAPEUTIC EXCHANGE PLASMA	15								
SOURCE LEUKOCYTES	16								
SOURCE PLASMA	17								
RECOVERED PLASMA	18								
BLOOD PRODUCTS FOR DIAGNOSTIC USE	19								
BLOOD BANK REAGENTS	20								
OTHER	21								