


DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION <b>BLOOD ESTABLISHMENT REGISTRATION AND PRODUCT LISTING</b>	<b>1. REGISTRATION NUMBER</b> FEI: 2275064 CFN: 2275064 <b>2. U.S. LICENSE NUMBER</b> 274	<b>3. REASON FOR SUBMISSION</b> .1 <input checked="" type="checkbox"/> ANNUAL REGISTRATION .2 <input type="checkbox"/> INITIAL REGISTRATION .3 <input type="checkbox"/> CHANGE IN INFORMATION	<b>FOR FDA USE ONLY</b>  DISTRICT OFFICE: New Jersey VALIDATED BY FDA: 29-NOV-2017 PRINTED BY FDA: 12-DEC-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 33.3(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)

Bergen Community Regional Blood Center  
 102 Chestnut Ridge Road  
 Montvale, NJ 07645

4.1 PHONE 201-444-3900

**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.)

dba Community Blood Services

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

**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