

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

1. REGISTRATION NUMBER
FEI: 2572105
CFN: 2572105

2. U.S. LICENSE NUMBER
983

3. REASON FOR SUBMISSION
 ANNUAL REGISTRATION
 INITIAL REGISTRATION
 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: Philadelphia
VALIDATED BY FDA: 18-NOV-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)

Community Blood Bank of Erie County
2646 Peach Street
Erie, PA 16508

4.1 PHONE 814-456-4206

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.)

Community Blood Bank of Northwest Pennsylvania
Community Blood Bank of Western New York

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

Community Blood Bank of Erie County
ATTN: Diane T. Pirschel
2646 Peach Street
Erie, PA 16508

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

Diane T. Pirschel

8.1 TYPED NAME Diane T. Pirschel
8.2 E-MAIL ADDRESS diane.pirschel@fourhearts.org
8.3 PHONE 814-456-4206 x135 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	ALLOGENEIC	AUTOLOGOUS	DIRECTED	COLLECT	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	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	1 <input checked="" type="checkbox"/>								
RED BLOOD CELLS (RBC)				2			<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>				<input checked="" type="checkbox"/>
RBC FROZEN				3								<input checked="" type="checkbox"/>
RBC DEGLYCEROLIZED				4								
RBC REJUVENATED				5								
RBC REJUVENATED FROZEN				6								
RBC REJUVENATED DEGLYCEROLIZED				7								
CRYOPRECIPITATED AHF				8			<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"/>
LEUKOCYTES/GRANULOCYTES				10								
PLASMA				11			<input checked="" type="checkbox"/>					<input checked="" type="checkbox"/>
PLASMA CRYOPRECIPITATE REDUCED				12			<input checked="" type="checkbox"/>					<input checked="" type="checkbox"/>
FRESH FROZEN PLASMA				13			<input checked="" type="checkbox"/>					<input checked="" type="checkbox"/>
LIQUID PLASMA				14								
THERAPEUTIC EXCHANGE PLASMA				15								
SOURCE LEUKOCYTES				16								
SOURCE PLASMA				17								
RECOVERED PLASMA				18			<input checked="" type="checkbox"/>					<input checked="" type="checkbox"/>
BLOOD PRODUCTS FOR DIAGNOSTIC USE				19								
BLOOD BANK REAGENTS				20								
OTHER				21								