

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
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.

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 dpirschel@fourhearts.org
8.3 PHONE 814-456-4206 x135
8.4 DATE

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)).

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
- 5. HOSPITAL TRANSFUSION SERVICE
 - a. INDEPENDENT
 - ASSOCIATED W/ COMMUNITY or HOSPITAL BLOOD BANK
 - b. 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	AUTOMATED APHERESIS	PREPARE	LEUKOCYTES REDUCED	IRRADIATED	DONOR RETESTED	TEST	STORE AND DISTRIBUTE TO OTHERS
(X)	(X)	(X)	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
			1 X								X
			2		X	X	X				X
			3								
			4								
			5								
			6								
			7								
			8			X	X				X
			9		X	X	X				X
			10								
			11			X					X
			12			X					X
			13			X					X
			14								
			15								
			16								
			17								
			18			X					X
			19								
			20								
			21								