

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

1. REGISTRATION NUMBER
FEL: 2573135
CFN: 2573135

2. U.S. LICENSE NUMBER
454

3. REASON FOR SUBMISSION
1. ANNUAL REGISTRATION
2. INITIAL REGISTRATION
3. CHANGE IN INFORMATION



DISTRICT OFFICE: Philadelphia
VALIDATED BY FDA: 30-NOV-2011
PRINTED BY FDA: 12-DEC-2011

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)

HCS-C-Blood Center
1465 Valley Center Parkway
Bethlehem, PA 18017

4.1 PHONE 610-691-5850

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.)

Miller Memorial Blood Center
Miller-Keystone Blood Center

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

HCS-C-Blood Center
ATTN: Abraham C. Garcia
1465 Valley Center Parkway
Bethlehem, PA 18017

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

Abraham C. Garcia
12-15-2011

8.1 TYPED NAME Abraham C. Garcia
8.2 E-MAIL ADDRESS agarcia@hosc.org
8.3 PHONE 610-691-5850 x1243

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 333(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. INDEPENDENT
- 6. ASSOCIATED W/ COMMUNITY or HOSPITAL BLOOD BANK
- 7. HOSPITAL TRANSFUSION SERVICE
- 8. APPROVED FOR MEDICARE REIMBURSEMENT
- 9. NOT APPROVED FOR MEDICARE REIMBURSEMENT
- 10. COMPONENT PREPARATION FACILITY
- 11. COLLECTION FACILITY
- 12. DISTRIBUTION CENTER
- 13. BROKERWAREHOUSE
- 14. OTHER (Specify): _____

U.S. LICENSE NUMBER OF PARENT FIRM

11. PRODUCTS	ALLOGENEIC	AUTOLOGOUS	DIRECTED	COLLECT (1)	MANUAL APHERESIS (2)	AUTOMATED APHERESIS (3)	PREPARE (4)	LEUCOCYTES REDUCED (5)	IRRADIATED (6)	DONOR RETESTED (7)	TEST (8)	STORE and DISTRIBUTE to OTHERS (9)
WHOLE BLOOD				X					X			X
RED BLOOD CELLS (RBC)						X	X	X	X			X
RBC FROZEN						X	X	X	X			X
RBC DEGLYCEROLIZED						X	X	X	X			X
RBC RELUVENATED						X	X	X	X			X
RBC RELUVENATED FROZEN						X	X	X	X			X
RBC RELUVENATED DEGLYCEROLIZED						X	X	X	X			X
CRYOPRECIPITATED AHF						X	X	X	X			X
PLATELETS						X	X	X	X			X
LEUCOCYTES/GRANULOCYTES												
PLASMA							X	X	X			X
PLASMA CRYOPRECIPITATE REDUCED							X	X	X			X
FRESH FROZEN PLASMA							X	X	X			X
LIQUID PLASMA							X	X	X			X
THERAPEUTIC EXCHANGE PLASMA												
SOURCE LEUCOCYTES												
SOURCE PLASMA												
RECOVERED PLASMA							X				X	X
BLOOD PRODUCTS FOR DIAGNOSTIC USE												
BLOOD BANK REAGENTS												
OTHER												