

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

1. REGISTRATION NUMBER
FEI: 3008740553
CFN:
2. U.S. LICENSE NUMBER
454

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

FOR FDA USE ONLY
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)

HCSC-Blood Center
128 Eagleview Blvd.
A-1B
Lionville Shopping Center
Lionville, PA 19353

4.1 PHONE 484-875-8015

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-Keystone Blood Center

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

HCSC-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@hcsc.org
8.3 PHONE 610-691-5850 x1243

8.4 DATE

This form is authorized by Sections 510(b), (i) and 704 of the Federal Food, Drug, and Cosmetic Act (Title 21, United States Code 360(b), (i) 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

- SINGLE PROPRIETORSHIP
- PARTNERSHIP
- CORPORATION profit non-profit
- COOPERATIVE ASSOCIATION
- FEDERAL (non-military)
- U.S. MILITARY
- STATE
- COUNTY/MUNICIPAL/HOSPITAL AUTHORITY
- OTHER (Specify):

10. TYPE ESTABLISHMENT (Check all boxes that describe routine or autologous operations.)

- COMMUNITY (NON-HOSPITAL) BLOOD BANK
- HOSPITAL BLOOD BANK
- PLASMAPHERESIS CENTER
- PRODUCT TESTING LABORATORY
- INDEPENDENT
- ASSOCIATED w/ COMMUNITY or HOSPITAL BLOOD BANK
- HOSPITAL TRANSFUSION SERVICE
- APPROVED FOR MEDICARE REIMBURSEMENT
- NOT APPROVED FOR MEDICARE REIMBURSEMENT
- COMPONENT PREPARATION FACILITY
- COLLECTION FACILITY
- DISTRIBUTION CENTER
- BROKER/WAREHOUSE
- OTHER (Specify):

11. PRODUCTS	ALLOGENIC	AUTOLOGOUS	DIRECTED	COLLECT	MANUAL APPERESIS	AUTOMATED APPERESIS	PREPARE	LEUKOCYTES REDUCED	IRRADIATED	DONOR TESTED	TEST	STORE and DISTRIBUTION OTHERS
				(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
WHOLE BLOOD	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>								
RED BLOOD CELLS (RBC)						<input checked="" type="checkbox"/>						
RBC FROZEN												
RBC DEGLYCEROLIZED												
RBC REJUVENATED												
RBC REJUVENATED FROZEN												
RBC REJUVENATED DEGLYCEROLIZED												
CRYOPRECIPITATED AHF												
PLATELETS						<input checked="" type="checkbox"/>						
LEUKOCYTES/GRANULOCYTES												
PLASMA												
PLASMA CRYOPRECIPITATE REDUCED												
FRESH FROZEN PLASMA						<input checked="" type="checkbox"/>						
LIQUID PLASMA												
THERAPEUTIC EXCHANGE PLASMA												
SOURCE LEUKOCYTES												
SOURCE PLASMA												
RECOVERED PLASMA												
BLOOD PRODUCTS FOR DIAGNOSTIC USE												
BLOOD BANK REAGENTS												
OTHER												