

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

1. REGISTRATION NUMBER
FEI: 3006116291
CFN:
2. U.S. LICENSE NUMBER
274

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

FOR FDA USE ONLY
5
DISTRICT OFFICE: New York
VALIDATED BY FDA: 22-DEC-2009
PRINTED BY FDA: 22-DEC-2009



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)

Bergen Community Regional Blood Center
20 Grand Street
Warwick, NY 10990

4.1 PHONE 201-444-3900

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.)

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

Bergen Community Regional Blood Center
ATTN: Dennis M. Todd, Ph.D.
973 Linwood Ave. West
Paramus, NJ 07653

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 Dennis M. Todd, Ph.D.
8.2 E-MAIL ADDRESS dentist@cbsblood.org
8.3 PHONE 201-444-3900
8.4 DATE 1/26/2010

This form is authorized by Sections 510(b), (f) and 704 of the Federal Food, Drug, and Cosmetic Act (Title 21, United States Code 360(b), (f) 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 HOSPITAL TRANSFUSION SERVICE
- 6 ASSOCIATED w/ COMMUNITY or HOSPITAL BLOOD BANK
- 7 NOT APPROVED FOR MEDICARE REIMBURSEMENT
- 8 COMPONENT PREPARATION FACILITY
- 9 COLLECTION FACILITY
- 10 DISTRIBUTION CENTER
- 11 BROKER/WAREHOUSE
- 12 OTHER (Specify):

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

U.S. LICENSE NUMBER OF PARENT FIRM
274