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

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.**

1. **REGISTRATION NUMBER**
   - FEI: 1048067
   - CFN: 1048067

2. **U.S. LICENSE NUMBER**
   - 1605

3. **REASON FOR SUBMISSION**
   - □ Initial Registration
   - □ Annual Registration
   - □ Change in Information

4. **LEGAL NAME AND LOCATION**
   - (Include legal name, number and street, city, state, country, and post office code)
   - Blood Connection, Inc. (The)
   - Blood Connection, Incorporated (The)
   - 1099 Bracken Road
   - Piedmont, SC 29673

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)
   - The Blood Connection, Incorporated (The)
   - ATTN: Denise Calloway, Vice President, Quality Systems
   - 1099 Bracken Road
   - Piedmont, SC 29673

7. **U.S. AGENT**
   - (Include name, institution name if applicable, number and street, city, state, and zip code)

8. **REPORTING OFFICIAL’S SIGNATURE**
   - □ Single Proprietorship
   - □ Partnership
   - □ Corporation
   - □ Cooperative Association
   - □ Federal (non-military)
   - □ U.S. Military
   - □ State
   - □ County/Municipal/Hospital Authority
   - □ Other (Specify):

9. **PRODUCTS**
   - □ Red Blood Cells (RBC)
   - □ RBC Frozen
   - □ RBC DeGlucerolized
   - □ RBC Rejuvenated
   - □ RBC Rejuvenated Frozen
   - □ RBC Rejuvenated DeGlcerolized
   - □ Cryoprecipitated AHF
   - □ Platelets
   - □ Leukocytes/Granulocytes
   - □ Plasma
   - □ 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

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

### 11. PRODUCTS

| Product                | Collect | Manual Apheresis | Automated Apheresis | Prepar |2| Leukocytes Reduced | Irradiated | Donor Retested | Test | Store and Distribute to Others |
|------------------------|---------|------------------|---------------------|--------|-------------------|------------|-----------------|------|---------------------------------|
| Whole Blood (WBC)      |         |                  |                     |        |                   |            |                 |      |                                 |
| Red Blood Cells (RBC)  |         |                  |                     |        |                   |            |                 |      |                                 |
| RBC Frozen             |         |                  |                     |        |                   |            |                 |      |                                 |
| RBC DeGlucerolized     |         |                  |                     |        |                   |            |                 |      |                                 |
| RBC Rejuvenated        |         |                  |                     |        |                   |            |                 |      |                                 |
| RBC Rejuvenated Frozen |         |                  |                     |        |                   |            |                 |      |                                 |
| RBC Rejuvenated DeGlcerolized | | | | | | | | | |
| Cryoprecipitated AHF   |         |                  |                     |        |                   |            |                 |      |                                 |
| Platelets              | X       |                  |                     |        |                   |            |                 |      |                                 |
| Leukocytes/Granulocytes|         |                  |                     |        |                   |            |                 |      |                                 |
| Plasma                 |         |                  |                     |        |                   |            |                 |      |                                 |
| 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                  |         |                  |                     |        |                   |            |                 |      |                                 |

### 9. TYPE OF OWNERSHIP

- □ Single Proprietorship
- □ Partnership
- ✔ Corporation (Non-profit)
- □ Cooperative Association
- □ Federal (Non-military)
- □ U.S. Military
- □ State
- □ County/Municipal/Hospital Authority
- □ Other (Specify): 

### 10. TYPE ESTABLISHMENT

- □ Community (Non-Hospital) Blood Bank
- □ Hospital Blood Bank
- □ Plasmapheresis Center
- □ Product Testing Laboratory
  - □ Independent
  - □ Associated with Community or Hospital Blood Bank
  - □ Approved for Medicare Reimbursement
  - □ Not Approved for Medicare Reimbursement
- □ Component Preparation Facility
- □ Collection Facility
- □ Distribution Center
- □ Broker/Warehouse
- □ Other (Specify):

### 11. PRODUCTS

- □ Allogeneic
- □ Autologous
- □ Directed

- □ Whole Blood
- □ Red Blood Cells (RBC)
- □ RBC Frozen
- □ RBC DeGlucerolized
- □ RBC Rejuvenated
- □ RBC Rejuvenated Frozen
- □ RBC Rejuvenated DeGlcerolized
- □ Cryoprecipitated AHF
- □ Platelets
- □ Leukocytes/Granulocytes
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- □ Therapeutic Exchange Plasma
- □ Source Leukocytes
- □ Source Plasma
- □ Recovered Plasma
- □ Blood Products for Diagnostic Use
- □ Blood Bank Reagents
- □ Other

### 12. STORE AND DISTRIBUTE TO OTHERS

- □ Yes
- □ No

### Footer Information

- **District Office:** Atlanta
- **Validated by FDA:** 30-Dec-2015
- **Printed by FDA:** 08-Jan-2016

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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)).