


| | | | |
|---|--|--|---|
| DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION BLOOD ESTABLISHMENT REGISTRATION AND PRODUCT LISTING | 1. REGISTRATION NUMBER FEI: 3019844 CFN: 3019844 2. U.S. LICENSE NUMBER 2042 | 3. REASON FOR SUBMISSION .1 <input checked="" type="checkbox"/> ANNUAL REGISTRATION .2 <input type="checkbox"/> INITIAL REGISTRATION .3 <input type="checkbox"/> 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.

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)).

DISTRICT OFFICE: Seattle
 VALIDATED BY FDA: 01-JAN-2016
 PRINTED BY FDA: 11-FEB-2016

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)

Bloodworks
 130 Andover Park E Suite 102
 Tukwila, WA 98188-2990

4.1 PHONE 206-241-6300

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
 a. ___ INDEPENDENT
 ___ ASSOCIATED W/ COMMUNITY or HOSPITAL BLOOD BANK
 .5 HOSPITAL TRANSFUSION SERVICE
 a. ___ 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) : _____

} 2042
 U.S. LICENSE NUMBER OF PARENT FIRM

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.)

Puget Sound Blood Center and Program
 Tukwila Center

| 11. PRODUCTS | COLLECT (.1) | MANUAL APHERESIS (.2) | AUTOMATED APHERESIS (.3) | PREPARE (.4) | LEUKOCYTES REDUCED (.5) | IRRADIATED (.6) | DONOR RETESTED (.7) | TEST (.8) | STORE and DISTRIBUTE to OTHERS (.9) |
|-----------------------------------|-----------------|--------------------------|-----------------------------|-----------------|----------------------------|--------------------|------------------------|--------------|--|
| | | | | | | | | | |
| WHOLE BLOOD | 1 | X | | | | | | | |
| RED BLOOD CELLS (RBC) | 2 | | X | | | | | | |
| RBC FROZEN | 3 | | | | | | | | |
| RBC DEGLYCEROLIZED | 4 | | | | | | | | |
| RBC REJUVENATED | 5 | | | | | | | | |
| RBC REJUVENATED FROZEN | 6 | | | | | | | | |
| RBC REJUVENATED DEGLYCEROLIZED | 7 | | | | | | | | |
| CRYOPRECIPITATED AHF | 8 | | | | | | | | |
| PLATELETS | 9 | | X | | | | | | |
| LEUKOCYTES/GRANULOCYTES | 10 | | | | | | | | |
| PLASMA | 11 | | | | | | | | |
| PLASMA CRYOPRECIPITATE REDUCED | 12 | | | | | | | | |
| FRESH FROZEN PLASMA | 13 | | X | | | | | | |
| LIQUID PLASMA | 14 | | | | | | | | |
| THERAPEUTIC EXCHANGE PLASMA | 15 | | | | | | | | |
| SOURCE LEUKOCYTES | 16 | | | | | | | | |
| SOURCE PLASMA | 17 | | | | | | | | |
| RECOVERED PLASMA | 18 | | | | | | | | |
| BLOOD PRODUCTS FOR DIAGNOSTIC USE | 19 | X | | | | | | | |
| BLOOD BANK REAGENTS | 20 | | | | | | | | |
| OTHER | 21 | | | | | | | | |

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

ATTN: Lisa R. Upshaw, Regulatory and Compliance Manager
 921 Terry Avenue
 Seattle, WA 98104-1239

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 Lisa R. Upshaw, Regulatory and Compliance Manager
 8.2 E-MAIL ADDRESS lisau@BloodworksNW.Org
 8.3 PHONE 206-292-6500
 8.4 DATE