


DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION BLOOD ESTABLISHMENT REGISTRATION AND PRODUCT LISTING		1. REGISTRATION NUMBER FEI: 3071347 CFN: 3071347 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  DISTRICT OFFICE: Seattle VALIDATED BY FDA: 22-DEC-2016 PRINTED BY FDA: 18-JAN-2017																																																																																																																																																																																																																																															
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)).																																																																																																																																																																																																																																																	
ENTER ALL CHANGES IN RED INK AND CIRCLE.		9. TYPE OF OWNERSHIP .1 <input type="checkbox"/> SINGLE PROPRIETORSHIP .2 <input type="checkbox"/> PARTNERSHIP .3 <input checked="" type="checkbox"/> CORPORATION profit___ non-profit <input checked="" type="checkbox"/> .4 <input type="checkbox"/> COOPERATIVE ASSOCIATION .5 <input type="checkbox"/> FEDERAL (non-military) .6 <input type="checkbox"/> U.S. MILITARY .7 <input type="checkbox"/> STATE .8 <input type="checkbox"/> COUNTY/MUNICIPAL/HOSPITAL AUTHORITY .9 <input type="checkbox"/> OTHER (Specify) : _____		10. TYPE ESTABLISHMENT (Check all boxes that describe routine or autologous operations.) .1 <input checked="" type="checkbox"/> COMMUNITY (NON-HOSPITAL) BLOOD BANK .2 <input type="checkbox"/> HOSPITAL BLOOD BANK .3 <input type="checkbox"/> PLASMAPHERESIS CENTER .4 <input type="checkbox"/> PRODUCT TESTING LABORATORY a. ___ INDEPENDENT ___ ASSOCIATED W/ COMMUNITY or HOSPITAL BLOOD BANK .5 <input type="checkbox"/> HOSPITAL TRANSFUSION SERVICE a. ___ APPROVED FOR MEDICARE REIMBURSEMENT ___ NOT APPROVED FOR MEDICARE REIMBURSEMENT .6 <input type="checkbox"/> COMPONENT PREPARATION FACILITY .7 <input type="checkbox"/> COLLECTION FACILITY .8 <input type="checkbox"/> DISTRIBUTION CENTER .9 <input type="checkbox"/> BROKER/WAREHOUSE .10 <input type="checkbox"/> OTHER (Specify) : _____ } U.S. LICENSE NUMBER OF PARENT FIRM _____																																																																																																																																																																																																																																															
4. LEGAL NAME AND LOCATION (Include legal name, number and street, city, state, country, and post office code) Bloodworks 921 Terry Avenue Seattle, WA 98104-1239 4.1 PHONE _____		11. PRODUCTS <table border="1" style="width:100%; border-collapse: collapse; font-size: x-small;"> <thead> <tr> <th style="width: 40%;"></th> <th style="width: 5%;">COLLECT</th> <th style="width: 5%;">MANUAL APHERESIS</th> <th style="width: 5%;">AUTOMATED APHERESIS</th> <th style="width: 5%;">PREPARE</th> <th style="width: 5%;">LEUKOCYTES REDUCED</th> <th style="width: 5%;">IRRADIATED</th> <th style="width: 5%;">DONOR RETESTED</th> <th style="width: 5%;">TEST</th> <th style="width: 5%;">STORE and DISTRIBUTE to OTHERS</th> </tr> <tr> <th style="text-align: center;"> <input checked="" type="checkbox"/> ALLOGENEIC <input checked="" type="checkbox"/> AUTOLOGOUS <input checked="" type="checkbox"/> DIRECTED </th> <th style="text-align: center;">(1)</th> <th style="text-align: center;">(2)</th> <th style="text-align: center;">(3)</th> <th style="text-align: center;">(4)</th> <th style="text-align: center;">(5)</th> <th style="text-align: center;">(6)</th> <th style="text-align: center;">(7)</th> <th style="text-align: center;">(8)</th> <th style="text-align: center;">(9)</th> </tr> </thead> <tbody> <tr><td>WHOLE BLOOD</td><td style="text-align: center;">1</td><td style="text-align: center;">X</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>RED BLOOD CELLS (RBC)</td><td style="text-align: center;">2</td><td></td><td style="text-align: center;">X</td><td></td><td></td><td style="text-align: center;">X</td><td></td><td style="text-align: center;">X</td><td style="text-align: center;">X</td></tr> <tr><td>RBC FROZEN</td><td style="text-align: center;">3</td><td></td><td></td><td style="text-align: center;">X</td><td></td><td></td><td></td><td style="text-align: center;">X</td><td style="text-align: center;">X</td></tr> <tr><td>RBC DEGLYCEROLIZED</td><td style="text-align: center;">4</td><td></td><td></td><td style="text-align: center;">X</td><td></td><td style="text-align: center;">X</td><td></td><td style="text-align: center;">X</td><td 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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.) Central Seattle King County Central Blood Bank		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 Manage 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 Manage 8.2 E-MAIL ADDRESS lisau@BloodworksNW.Org 8.3 PHONE _____ 8.4 DATE _____																																																																																																																																																																																																																																																			