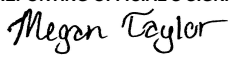


DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION <b>ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES,          AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/Ps)</b> (See reverse side for instructions)		<b>1. REGISTRATION NUMBER</b> (FDA Establishment Identifier)  FEI: 3000243835	<b>2. REASON FOR SUBMISSION</b> a. <input type="checkbox"/> INITIAL REGISTRATION / LISTING b. <input checked="" type="checkbox"/> ANNUAL REGISTRATION / LISTING c. <input type="checkbox"/> CHANGE IN INFORMATION d. <input type="checkbox"/> INACTIVE	<b>VALIDATION--FOR FDA USE ONLY</b> VALIDATED BY FDA:20-NOV-2015 DISTRICT: Minneapolis PRINTED BY FDA:03-DEC-2015	
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<b>PART I - ESTABLISHMENT INFORMATION</b> <b>3. OTHER FDA REGISTRATIONS</b> a. BLOOD FDA 2830 NO. _____ b. DEVICES FDA 2891 NO. _____ c. DRUG FDA 2656 NO. _____ <b>4. PHYSICAL LOCATION</b> (Include legal name, number and street, city, state, country, and post office code) Fairfax Cryobank, Inc.  1944 Lexington Avenue North Roseville, Minnesota 55113  a. PHONE 800-466-2796 EXT _____ b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY		<b>PART II - PRODUCT INFORMATION</b> <b>10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps</b> <table border="1" style="width:100%; border-collapse: collapse;"> <tr> <th rowspan="2" style="width:20%;">Types of HCT / Ps</th> <th colspan="8">Establishment Functions</th> <th rowspan="2" style="width:5%;">11. HCT/Ps DESCRIBED IN 21 CFR 1271.10</th> <th rowspan="2" style="width:5%;">12. HCT/Ps REGULATED AS MEDICAL DEVICES</th> <th rowspan="2" style="width:5%;">13. HCT/Ps REGULATED AS DRUGS OR BIOLOGICAL DRUGS</th> <th rowspan="2" style="width:15%;">14. PROPRIETARY NAME(S)</th> </tr> <tr> <th>Recover</th> <th>Screen</th> <th>Test</th> <th>Package</th> <th>Process</th> <th>Store</th> <th>Label</th> <th>Distribute</th> </tr> <tr><td>a. Bone</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>b. Cartilage</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>c. Cornea</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>d. Dura Mater</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>e. 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<b>5. ENTER CORRECTIONS TO ITEM 4</b>  <b>6. MAILING ADDRESS OF REPORTING OFFICIAL</b> (Include institution name if applicable, number and street, city, state, country, and post office code) Fairfax Cryobank, Inc. - Roseville Attn: Megan Taylor 3015 Williams Drive Suite 110 Fairfax, Virginia 22031  a. PHONE 800-338-8407 EXT _____		<b>7. ENTER CORRECTIONS TO ITEM 6</b> b. PHONE _____																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																						
<b>8. U.S. AGENT</b>  a. E-MAIL _____		<b>9. REPORTING OFFICIAL'S SIGNATURE</b>  a. TYPED NAME Megan Taylor b. E-MAIL mtaylor@givf.com c. TITLE Document Administrator d. DATE 19-NOV-2015																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																						