

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/PS) <i>(See reverse side for instructions)</i>		1. REGISTRATION NUMBER (Field Establishment Identifier) FEI: 0001570984	2. REASON FOR SUBMISSION 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		VALIDATION—FOR FDA USE ONLY VALIDATED BY FDA:30-DEC-2008 DISTRICT: Cincinnati PRINTED BY FDA:05-JAN-2009																																																																																																																																																																																																																																																
PART I - ESTABLISHMENT INFORMATION		PART II - PRODUCT INFORMATION							11. HCT/PS DESCRIBED IN 21 CFR 1271.10 12. HCT/PS REGULATED AS MEDICAL DEVICES 13. HCT/PS REGULATED AS BIOLOGICAL DRUGS	14. PROPRIETARY NAME(S)																																																																																																																																																																																																																																											
3. OTHER FDA REGISTRATIONS a. BLOOD FDA 2830 NO. FEI: 0001570984 b. DEVICES FDA 2891 NO. _____ c. DRUG FDA 2656 NO. _____		10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps <table border="1" style="width:100%; border-collapse: collapse; font-size: x-small;"> <thead> <tr> <th rowspan="2" style="text-align: center;">Types of HCT / Ps</th> <th colspan="8" style="text-align: center;">Establishment Functions</th> </tr> <tr> <th style="text-align: center;">Recover</th> <th style="text-align: center;">Screen</th> <th style="text-align: center;">Test</th> <th style="text-align: center;">Package</th> <th style="text-align: center;">Process</th> <th style="text-align: center;">Store</th> <th style="text-align: center;">Label</th> <th style="text-align: center;">Distribute</th> </tr> </thead> <tbody> <tr> <td>a. 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Peripheral Blood Stem Cells <input checked="" type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic</td> <td style="text-align: center;">X</td> <td style="text-align: center;">X</td> <td style="text-align: center;">X</td> <td style="text-align: center;">X</td> <td style="text-align: center;">X</td> <td style="text-align: center;">X</td> <td style="text-align: center;">X</td> <td style="text-align: center;">X</td> <td style="text-align: center;">X</td> </tr> <tr> <td>l. Sclera</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>m. Semen <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>n. 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4. PHYSICAL LOCATION <i>(Include legal name, number and street, city, state, country, and post office code)</i> Community Blood Center dba Community Tissue Services 349 S. Main Street Dayton, Ohio 45402 a. PHONE 937-461-3450 EXT 3610 b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY		5. ENTER CORRECTIONS TO ITEM 4																																																																																																																																																																																																																																																			
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8. U.S. AGENT a. E-MAIL _____		9. REPORTING OFFICIAL'S SIGNATURE a. TYPED NAME David M. Smith, MD b. E-MAIL dsmith@cbcts.org c. TITLE CEO/Medical Director d. DATE 08-DEC-2008																																																																																																																																																																																																																																																			