

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: 1000305999	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 1 *1000305999* VALIDATED By FDA:12/20/07 PRINTED By FDA:12/28/07 DISTRICT: Cincinnati
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PART I - ESTABLISHMENT INFORMATION	PART II - PRODUCT INFORMATION																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																	
3. OTHER FDA REGISTRATIONS a. BLOOD FDA 2830 NO. _____ 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;"> <thead> <tr> <th rowspan="2" style="width:30%;">Types of HCT / Ps</th> <th colspan="8" style="text-align: center;">Establishment Functions</th> <th rowspan="2" style="writing-mode: vertical-rl; transform: rotate(180deg);">11. HCT/PS DESCRIBED IN 21 CFR 1271.10</th> <th rowspan="2" style="writing-mode: vertical-rl; transform: rotate(180deg);">12. HCT/PS REGULATED AS MEDICAL DEVICES</th> <th rowspan="2" style="writing-mode: vertical-rl; transform: rotate(180deg);">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> </thead> <tbody> <tr> <td>No HCT / P Specified</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>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></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></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></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></tr> <tr><td>e. 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4. PHYSICAL LOCATION <i>(Include legal name, number and street, city, state, country, and post office code)</i> AlloSource 2939 Vernon Place Cincinnati, Ohio 45219-2430 a. PHONE 513-558-6400 EXT 6179 b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																		
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6. MAILING ADDRESS OF REPORTING OFFICIAL <i>(Include institution name if applicable, number and street, city, state, country, and post office code)</i> AlloSource Attn: Kerry L. Chunko 6278 S. Troy Circle Centennial, Colorado 80111 a. PHONE 720-873-4713 EXT _____																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																		
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9. REPORTING OFFICIAL'S SIGNATURE a. TYPED NAME Kerry L. Chunko b. E-MAIL kchunko@allosource.org c. TITLE RA/QA Director d. DATE 19-DEC-2007																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																		