

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> <i>(See reverse side for instructions)</i>	<b>1. REGISTRATION NUMBER</b> (Field Establishment Identifier)  FEI: 3000215346	<b>2. REASON FOR SUBMISSION</b> a. <input type="checkbox"/> INITIAL REGISTRATION / LISTING b. <input type="checkbox"/> ANNUAL REGISTRATION / LISTING c. <input checked="" type="checkbox"/> CHANGE IN INFORMATION d. <input type="checkbox"/> INACTIVE	VALIDATION--FOR FDA USE ONLY  * 3000215346 * VALIDATED By FDA:12/26/07 PRINTED By FDA:12/28/07 DISTRICT: Denver
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PART I - ESTABLISHMENT INFORMATION	PART II - PRODUCT INFORMATION		14. PROPRIETARY NAME(S)																																																																																																																																																																																																																																																																																																								
<b>3. OTHER FDA REGISTRATIONS</b> a. BLOOD FDA 2830 NO. _____ b. DEVICES FDA 2891 NO. _____ c. DRUG FDA 2656 NO. _____	<b>10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps</b> <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> </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 style="background-color: #cccccc;">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 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></td><td style="text-align: center;">X</td><td></td><td></td> </tr> <tr> <td>b. Cartilage</td> <td></td><td></td><td></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></td><td style="text-align: center;">X</td><td></td><td></td> </tr> <tr> <td>c. 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<b>4. PHYSICAL LOCATION</b> (Include legal name, number and street, city, state, country, and post office code) AlloSource Inc. 6278 S. Troy Circle Centennial, Colorado 80111  a. PHONE 720-873-0213 EXT _____ b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY																																																																																																																																																																																																																																																																																																											
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<b>6. MAILING ADDRESS OF REPORTING OFFICIAL</b> (Include institution name if applicable, number and street, city, state, country, and post office code) AlloSource Attn: Kerry L. Chunko 6278 S. Troy Circle Centennial, Colorado 80111  a. PHONE 720-873-4713 EXT _____																																																																																																																																																																																																																																																																																																											
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<b>9. REPORTING OFFICIAL'S SIGNATURE</b>  a. TYPED NAME Kerry L. Chunko b. E-MAIL kchunko@allosource.org c. TITLE RA/QA Director d. DATE 21-DEC-2007																																																																																																																																																																																																																																																																																																											