

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: 3002851781	<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	VALIDATION--FOR FDA USE ONLY  * 3002851781 * VALIDATED By FDA:12/20/07 PRINTED By FDA:12/28/07 DISTRICT: Los Angeles
--	--	--	--

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 colspan="12" style="background-color: #cccccc;"><b>No HCT / P Specified</b></td> </tr> <tr><td>a. Bone</td><td></td><td></td><td></td><td></td><td></td><td>X</td><td></td><td>X</td><td>X</td><td></td><td></td></tr> <tr><td>b. Cartilage</td><td></td><td></td><td></td><td></td><td></td><td>X</td><td></td><td>X</td><td>X</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. Embryo</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></td> <td colspan="11"> <input type="checkbox"/> SIP  <input type="checkbox"/> Directed  <input type="checkbox"/> Anonymous                 </td> </tr> <tr><td>f. Fascia</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>g. Heart Valve</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>h. Ligament</td><td></td><td></td><td></td><td></td><td></td><td>X</td><td></td><td>X</td><td>X</td><td></td><td></td></tr> <tr><td>i. Oocyte</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></td> <td colspan="11"> <input type="checkbox"/> SIP  <input type="checkbox"/> Directed  <input type="checkbox"/> Anonymous                 </td> </tr> <tr><td>j. Pericardium</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>k. Peripheral Blood Stem Cells</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></td> <td colspan="11"> <input type="checkbox"/> Autologous  <input type="checkbox"/> Family Related  <input type="checkbox"/> Allogeneic                 </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><td></td><td></td></tr> <tr><td>m. Semen</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></td> <td colspan="11"> <input type="checkbox"/> SIP  <input type="checkbox"/> Directed  <input type="checkbox"/> Anonymous                 </td> </tr> <tr><td>n. Skin</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>o. Somatic Cells</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></td> <td colspan="11"> <input type="checkbox"/> Autologous  <input type="checkbox"/> Family Related  <input type="checkbox"/> Allogeneic                 </td> </tr> <tr><td>p. Tendon</td><td></td><td></td><td></td><td></td><td></td><td>X</td><td></td><td>X</td><td>X</td><td></td><td></td></tr> <tr><td>q. Umbilical Cord Blood Stem Cells</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></td> <td colspan="11"> <input type="checkbox"/> Autologous  <input type="checkbox"/> Family Related  <input type="checkbox"/> Allogeneic                 </td> </tr> <tr><td>r. Vascular Graft</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>s.</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>t.</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>u.</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>v.</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> </tbody> </table>	Types of HCT / Ps	Establishment Functions								11. HCT/Ps DESCRIBED IN 21 CFR 1271.10	12. HCT/Ps REGULATED AS MEDICAL DEVICES	13. HCT/Ps REGULATED AS DRUGS OR BIOLOGICAL DRUGS	Recover	Screen	Test	Package	Process	Store	Label	Distribute	<b>No HCT / P Specified</b>												a. Bone						X		X	X			b. Cartilage						X		X	X			c. Cornea												d. Dura Mater												e. Embryo													<input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous											f. Fascia												g. Heart Valve												h. Ligament						X		X	X			i. Oocyte													<input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous											j. Pericardium												k. Peripheral Blood Stem Cells													<input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic											l. Sclera												m. Semen													<input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous											n. Skin												o. Somatic Cells													<input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic											p. Tendon						X		X	X			q. Umbilical Cord Blood Stem Cells													<input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic											r. Vascular Graft												s.												t.												u.												v.													
Types of HCT / Ps	Establishment Functions								11. HCT/Ps DESCRIBED IN 21 CFR 1271.10	12. HCT/Ps REGULATED AS MEDICAL DEVICES				13. HCT/Ps REGULATED AS DRUGS OR BIOLOGICAL DRUGS																																																																																																																																																																																																																																																																																																																																																																					
	Recover	Screen	Test	Package	Process	Store	Label	Distribute																																																																																																																																																																																																																																																																																																																																																																											
<b>No HCT / P Specified</b>																																																																																																																																																																																																																																																																																																																																																																																			
a. Bone						X		X	X																																																																																																																																																																																																																																																																																																																																																																										
b. Cartilage						X		X	X																																																																																																																																																																																																																																																																																																																																																																										
c. Cornea																																																																																																																																																																																																																																																																																																																																																																																			
d. Dura Mater																																																																																																																																																																																																																																																																																																																																																																																			
e. Embryo																																																																																																																																																																																																																																																																																																																																																																																			
	<input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous																																																																																																																																																																																																																																																																																																																																																																																		
f. Fascia																																																																																																																																																																																																																																																																																																																																																																																			
g. Heart Valve																																																																																																																																																																																																																																																																																																																																																																																			
h. Ligament						X		X	X																																																																																																																																																																																																																																																																																																																																																																										
i. Oocyte																																																																																																																																																																																																																																																																																																																																																																																			
	<input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous																																																																																																																																																																																																																																																																																																																																																																																		
j. Pericardium																																																																																																																																																																																																																																																																																																																																																																																			
k. Peripheral Blood Stem Cells																																																																																																																																																																																																																																																																																																																																																																																			
	<input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic																																																																																																																																																																																																																																																																																																																																																																																		
l. Sclera																																																																																																																																																																																																																																																																																																																																																																																			
m. Semen																																																																																																																																																																																																																																																																																																																																																																																			
	<input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous																																																																																																																																																																																																																																																																																																																																																																																		
n. Skin																																																																																																																																																																																																																																																																																																																																																																																			
o. Somatic Cells																																																																																																																																																																																																																																																																																																																																																																																			
	<input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic																																																																																																																																																																																																																																																																																																																																																																																		
p. Tendon						X		X	X																																																																																																																																																																																																																																																																																																																																																																										
q. Umbilical Cord Blood Stem Cells																																																																																																																																																																																																																																																																																																																																																																																			
	<input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic																																																																																																																																																																																																																																																																																																																																																																																		
r. Vascular Graft																																																																																																																																																																																																																																																																																																																																																																																			
s.																																																																																																																																																																																																																																																																																																																																																																																			
t.																																																																																																																																																																																																																																																																																																																																																																																			
u.																																																																																																																																																																																																																																																																																																																																																																																			
v.																																																																																																																																																																																																																																																																																																																																																																																			
<b>4. PHYSICAL LOCATION</b> <i>(Include legal name, number and street, city, state, country, and post office code)</i> AlloSource 9323 Chesapeake Drive Suite C1 San Diego, California 92123  a. PHONE 800-345-8024 EXT _____ b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY																																																																																																																																																																																																																																																																																																																																																																																			
<b>5. ENTER CORRECTIONS TO ITEM 4</b>																																																																																																																																																																																																																																																																																																																																																																																			
<b>6. MAILING ADDRESS OF REPORTING OFFICIAL</b> <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 _____																																																																																																																																																																																																																																																																																																																																																																																			
<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 Kerry L. Chunko b. E-MAIL kchunko@allosource.org c. TITLE RA/QA Director	d. DATE 19-DEC-2007																																																																																																																																																																																																																																																																																																																																																																																		