

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: 3005342355		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:02-JAN-2009 DISTRICT: Los Angeles 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 MANUFACTURED AS MEDICAL DEVICES 13. HCT/PS REGULATED AS DRUGS OR BIOLOGICAL DRUGS 14. PROPRIETARY NAME(S)																																																																																																																																																																																																																																																																																																																	
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">Types of HCT / Ps</th> <th colspan="8">Establishment Functions</th> <th rowspan="2">11. HCT/PS DESCRIBED IN 21 CFR 1271.10</th> <th rowspan="2">12. HCT/PS MANUFACTURED AS MEDICAL DEVICES</th> <th rowspan="2">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>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. Embryo</td><td></td><td></td><td></td><td></td><td></td><td>X</td><td></td><td></td><td>X</td><td>X</td><td></td><td></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><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><td></td></tr> <tr><td>h. Ligament</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>i. Oocyte</td><td></td><td></td><td></td><td></td><td></td><td>X</td><td></td><td></td><td></td><td>X</td><td></td><td></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><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><td></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><td></td></tr> <tr><td>m. Semen</td><td>X</td><td>X</td><td></td><td>X</td><td>X</td><td>X</td><td>X</td><td>X</td><td>X</td><td></td><td></td><td></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><td></td></tr> <tr><td>o. Somatic Cell Therapy Products</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>p. Tendon</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>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><td></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><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><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><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><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><td></td></tr> </tbody> </table>								Types of HCT / Ps	Establishment Functions								11. HCT/PS DESCRIBED IN 21 CFR 1271.10	12. HCT/PS MANUFACTURED AS MEDICAL DEVICES	13. HCT/PS REGULATED AS DRUGS OR BIOLOGICAL DRUGS	Recover	Screen	Test	Package	Process	Store	Label	Distribute	a. Bone													b. Cartilage													c. Cornea													d. Dura Mater													e. Embryo						X			X	X			f. Fascia													g. Heart Valve													h. Ligament													i. Oocyte						X				X			j. Pericardium													k. Peripheral Blood Stem Cells													l. Sclera													m. Semen	X	X		X	X	X	X	X	X				n. Skin													o. Somatic Cell Therapy Products													p. Tendon													q. Umbilical Cord Blood Stem Cells													r. Vascular Graft													s.													t.													u.													v.										
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4. PHYSICAL LOCATION <i>(Include legal name, number and street, city, state, country, and post office code)</i> California Cryobank, Inc. 11915 La Grange Avenue Los Angeles, California 90025-5213 a. PHONE 310-443-5244 EXT 1000 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		6. MAILING ADDRESS OF REPORTING OFFICIAL <i>(Include institution name if applicable, number and street, city, state, country, and post office code)</i> California Cryobank, Inc. Attn: Diana C. Schillinger 11915 La Grange Avenue Los Angeles, California 90025-5213 a. PHONE 310-443-5244 EXT 1160		7. ENTER CORRECTIONS TO ITEM 6		b. PHONE _____																																																																																																																																																																																																																																																																																																																	
8. U.S. AGENT a. E-MAIL _____		9. REPORTING OFFICIAL'S SIGNATURE a. TYPED NAME Diana C. Schillinger b. E-MAIL dschillinger@cryobank.com c. TITLE Compliance Manager		d. DATE 10-DEC-2008																																																																																																																																																																																																																																																																																																																					