

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: 3004104395	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 VALIDATED BY FDA:23-NOV-2011 DISTRICT: San Francisco PRINTED BY FDA:02-DEC-2011
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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 DRUGS OR BIOLOGICAL DRUGS	14. PROPRIETARY NAME(S)																					
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4. PHYSICAL LOCATION <i>(Include legal name, number and street, city, state, country, and post office code)</i> OneLegacy - Bakersfield 1100 Mohawk Street, Suite 150 Bakersfield, California 93309 a. PHONE 661-356-5244 EXT _____ b. <input checked="" type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. 3005879987) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY	a. Bone	X	X							X																
	b. Cartilage	X	X							X																
	c. Cornea	X	X							X																
	d. Dura Mater																									
	e. Embryo <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous																									
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	j. Pericardium	X	X							X																
6. MAILING ADDRESS OF REPORTING OFFICIAL <i>(Include institution name if applicable, number and street, city, state, country, and post office code)</i> OneLegacy Attn: Alan J. Cochran, MHA, CTBS 221 South Figueroa Street, Suite 500 Los Angeles, California 90012 a. PHONE 213-229-5662 EXT _____	k. Peripheral Blood Stem Cells <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic																									
	l. Sclera	X	X							X																
	m. Semen <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous																									
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	r. Vascular Graft	X	X							X																
	9. REPORTING OFFICIAL'S SIGNATURE a. TYPED NAME Alan J. Cochran, MHA, CTBS b. E-MAIL acochran@onelegacy.org c. TITLE VP, Quality Systems d. DATE 22-NOV-2011	s.																								
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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 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" style="width:30%;">Types of HCT / Ps</th> <th colspan="8" style="text-align: center;">Establishment Functions</th> <th rowspan="2">Recover</th> <th rowspan="2">Screen</th> <th rowspan="2">Test</th> <th rowspan="2">Package</th> <th rowspan="2">Process</th> <th rowspan="2">Store</th> <th rowspan="2">Label</th> <th rowspan="2">Distribute</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> </table>	Types of HCT / Ps	Establishment Functions								Recover	Screen	Test	Package	Process	Store	Label	Distribute	Recover	Screen	Test	Package	Process	Store	Label	Distribute				
Types of HCT / Ps	Establishment Functions								Recover	Screen									Test	Package	Process	Store	Label	Distribute						
	Recover	Screen	Test	Package	Process	Store	Label	Distribute																						
4. PHYSICAL LOCATION <i>(Include legal name, number and street, city, state, country, and post office code)</i> OneLegacy - Los Angeles 1001 Wilshire Blvd., Suite 200 Los Angeles, California 90017 a. PHONE (213) 989-2420 EXT _____ b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY	a. Bone	X	X																											
	b. Cartilage	X	X																											
	c. Cornea	X	X																											
	d. Dura Mater																													
	e. Embryo <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous																													
	f. Fascia	X	X																											
	g. Heart Valve	X	X																											
	h. Ligament	X	X																											
	i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous																													
	j. Pericardium	X	X																											
6. MAILING ADDRESS OF REPORTING OFFICIAL <i>(Include institution name if applicable, number and street, city, state, country, and post office code)</i> OneLegacy Attn: Alan J. Cochran, MHA, CTBS 221 South Figueroa Street, Suite 500 Los Angeles, California 90012 a. PHONE 213-229-5662 EXT _____	k. Peripheral Blood Stem Cells <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic																													
	l. Sclera	X	X																											
	m. Semen <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous																													
	n. Skin	X	X																											
	o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic																													
	p. Tendon	X	X																											
	q. Umbilical Cord Blood Stem Cells <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic																													
	r. Vascular Graft	X	X																											
	s.																													
	t.																													
9. REPORTING OFFICIAL'S SIGNATURE a. TYPED NAME Alan J. Cochran, MHA, CTBS b. E-MAIL acochran@onelegacy.org c. TITLE VP, Quality Systems d. DATE 22-NOV-2011	u.																													
	v.																													