

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: 3003351041	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: San Francisco 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 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											
4. PHYSICAL LOCATION <i>(Include legal name, number and street, city, state, country, and post office code)</i> California Cryobank, Inc. 700 Welch Rd. # 107 Palo Alto, California 94304 a. PHONE 650-324-1900 EXT _____ b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY		Types of HCT / Ps		Establishment Functions									
		Recover Screen Test Package Process Store Label Distribute	SIP <input checked="" type="checkbox"/> Directed <input type="checkbox"/> Anonymous	SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous	Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic	SIP <input checked="" type="checkbox"/> Directed <input checked="" type="checkbox"/> Anonymous	Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic	Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic	Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic	Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic	Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic		
5. ENTER CORRECTIONS TO ITEM 4		a. Bone											
6. MAILING ADDRESS OF REPORTING OFFICIAL <i>(Include institution name if applicable, number and street, city, state, country, and post office code)</i> Diana C. Schillinger Attn: Diana C. Schillinger 11915 LaGrange Avenue Los Angeles, California 90025 a. PHONE 310-443-5244 EXT 1160		b. Cartilage											
		c. Cornea											
7. ENTER CORRECTIONS TO ITEM 6		d. Dura Mater											
		e. Embryo						X				X	
8. U.S. AGENT a. E-MAIL _____		f. Fascia											
		g. Heart Valve											
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		h. Ligament											
		i. Oocyte											
		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.											