

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) FE#: 3003367577	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 * 3003367577 * VALIDATED By FDA: 12/03/07 PRINTED By FDA: 12/07/07 DISTRICT: New England													
PART I - ESTABLISHMENT INFORMATION		PART II - PRODUCT INFORMATION							11. HCT/Ps DESCRIBED IN 21 CFR 1271.18 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. 950 Massachusetts Ave. Cambridge, Massachusetts 02139 a. PHONE 617-497-8646 EXT 12 b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY		Establishment Functions															
		Types of HCT / Ps	Recover	Screen	Test	Package	Process	Store			Label	Distribute					
5. ENTER CORRECTIONS TO ITEM 4		No HCT / P Specified															
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, MT (ASCP) 950 Massachusetts Avenue Cambridge, Massachusetts 02139 a. PHONE 310-443-5244 EXT 1160		a. Bone															
		b. Cartilage															
7. ENTER CORRECTIONS TO ITEM 6		c. Cornea															
		d. Dura Mater															
8. U.S. AGENT a. E-MAIL 9. REPORTING OFFICIAL'S SIGNATURE a. TYPED NAME Diana C. Schillinger, MT (ASCP) b. E-MAIL dschillinger@cryobank.com c. TITLE Compliance Manager d. DATE 27-NOV-2007		e. Embryo <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous															
		f. Fascia															
		g. Heart Valve															
		h. Ligament															
		i. Oocytes <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 checked="" type="checkbox"/> SIP <input checked="" type="checkbox"/> Directed <input checked="" type="checkbox"/> Anonymous							X	X	X	X	X	X	X	X	X
		n. Skin															
		o. Somatic Cells <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic															
		p. Tendon															
		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.															