

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) (See reverse side for instructions)		1. REGISTRATION NUMBER (Field Establishment Identifier) FEI: 3003351041	2. REASON FOR SUBMISSION a. <input type="checkbox"/> INITIAL REGISTRATION / LISTING b. <input type="checkbox"/> ANNUAL REGISTRATION / LISTING c. <input checked="" type="checkbox"/> CHANGE IN INFORMATION d. <input type="checkbox"/> INACTIVE	VALIDATION--FOR FDA USE ONLY VALIDATED BY FDA:10-FEB-2011 DISTRICT: San Francisco PRINTED BY FDA:10-FEB-2011						
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 (Include legal name, number and street, city, state, country, and post office code) 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	Recover	Screen	Test	Package	Process	Store	Label	Distribute
		Establishment Functions								
5. ENTER CORRECTIONS TO ITEM 4		a. Bone								
		b. Cartilage								
6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code) California Cryobank, Inc. Attn: Rama Tyagi 11915 La Grange Avenue Los Angeles, California 90025-5213 a. PHONE 310-443-5244 EXT 1172		c. Cornea								
		d. Dura Mater								
7. ENTER CORRECTIONS TO ITEM 6		e. Embryo <input checked="" type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous						X		X
		f. Fascia								
b. PHONE _____		g. Heart Valve								
		h. Ligament								
8. U.S. AGENT a. E-MAIL _____		i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous								
		j. Pericardium								
9. REPORTING OFFICIAL'S SIGNATURE a. TYPED NAME Rama Tyagi b. E-MAIL rtyagi@cryobank.com c. TITLE Director, Quality/Regulatory Affairs d. DATE 08-FEB-2011		k. Peripheral Blood Stem <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
		n. Skin								
		o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic								
		p. Tendon								
		q. Umbilical Cord Blood <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic								
		r. Vascular Graft								
		s.								
		t.								
		u.								
		v.								