


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: 3003367577	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:11-FEB-2011 DISTRICT: New England PRINTED BY FDA:11-FEB-2011								
PART I - ESTABLISHMENT INFORMATION		PART II - PRODUCT INFORMATION			11. HCT/Ps 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										
		Establishment Functions										
		Recover	Screen	Test			Package	Process	Store	Label	Distribute	
4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code) California Cryobank, Inc. 950 Massachusetts Ave. Cambridge, Massachusetts 02139		a. Bone										
a. PHONE 617-497-8646 EXT _____ b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY		e. Embryo <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous										
5. ENTER CORRECTIONS TO ITEM 4		f. Fascia										
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		g. Heart Valve										
a. PHONE 310-443-5244 EXT 1172 7. ENTER CORRECTIONS TO ITEM 6		h. Ligament										
b. PHONE _____		i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous										
8. U.S. AGENT		j. Pericardium										
a. E-MAIL _____		k. Peripheral Blood Stem <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic										
9. REPORTING OFFICIAL'S SIGNATURE  a. TYPED NAME Rama Tyagi b. E-MAIL rtyagi@cryobank.com c. TITLE Director, Quality/Regulatory Affairs d. DATE 10-FEB-2011		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.										