

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: 3005202248	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 York PRINTED BY FDA: 11-FEB-2011	1							
PART I - ESTABLISHMENT INFORMATION		PART II - PRODUCT INFORMATION			11. HCT/Ps CS 03/09/10 CR 12/11/10 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. 369 Lexington Avenue, #401 New York, New York 10017		a. Bone										
a. PHONE 212-779-1608 EXT _____ b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY		b. Cartilage										
5. ENTER CORRECTIONS TO ITEM 4		c. Cornea										
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		d. Dura Mater										
a. PHONE 310-443-5244 EXT 1172 7. ENTER CORRECTIONS TO ITEM 6		e. Embryo <div style="font-size: x-small; margin-left: 20px;"> <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous </div>										
a. E-MAIL _____ 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		f. Fascia										
8. U.S. AGENT		g. Heart Valve										
		h. Ligament										
		i. Oocyte <div style="font-size: x-small; margin-left: 20px;"> <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous </div>										
		j. Pericardium										
		k. Peripheral Blood Stem <div style="font-size: x-small; margin-left: 20px;"> <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic </div>										
		l. Sclera										
		m. Semen <div style="font-size: x-small; margin-left: 20px;"> <input checked="" type="checkbox"/> SIP <input checked="" type="checkbox"/> Directed <input checked="" type="checkbox"/> Anonymous </div>	X	X		X	X	X	X	X		
		n. Skin										
		o. Somatic Cell Therapy Products <div style="font-size: x-small; margin-left: 20px;"> <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic </div>										
		p. Tendon										
		q. Umbilical Cord Blood <div style="font-size: x-small; margin-left: 20px;"> <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic </div>										
		r. Vascular Graft										
		s. Testicular Tissue		X		X	X	X	X	X		
		t.										
		u.										
		v.										