

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.  INITIAL REGISTRATION / LISTING  
 b.  ANNUAL REGISTRATION / LISTING  
 c.  CHANGE IN INFORMATION  
 d.  INACTIVE

**VALIDATION-FOR FDA USE ONLY**  
 1  
 VALIDATED BY FDA:29-NOV-2011  
 DISTRICT: New England  
 PRINTED BY FDA:02-DEC-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		10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps														
		Establishment Functions								Types of HCT / Ps						
		Recover	Screen	Test	Package	Process	Store	Label	Distribute							
a. BLOOD FDA 2830 NO. _____																
b. DEVICES FDA 2891 NO. _____																
c. DRUG FDA 2656 NO. _____																
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. Bone														
a. PHONE 617-497-8646 EXT _____		b. Cartilage														
b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____)		c. Cornea														
c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY		d. Dura Mater														
5. ENTER CORRECTIONS TO ITEM 4		e. Embryo <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous														
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: Rama Tyagi 11915 La Grange Avenue Los Angeles, California 90025-5213		f. Fascia														
a. PHONE 310-443-5244 EXT 1172		g. Heart Valve														
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 Cells <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic														
9. REPORTING OFFICIAL'S SIGNATURE		l. Sclera														
a. TYPED NAME Rama Tyagi		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					
b. E-MAIL rtyagi@cryobank.com		n. Skin														
c. TITLE Director, Quality/Regulatory Affairs		o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic														
d. DATE 28-NOV-2011		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.														

