

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

VALIDATION—FOR FDA USE ONLY
VALIDATED BY FDA:29-NOV-2011
DISTRICT: New York
PRINTED BY FDA:02-DEC-2011

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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. _____		a. Bone																
b. DEVICES FDA 2891 NO. _____		b. Cartilage																
c. DRUG FDA 2656 NO. _____		c. Cornea																
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		d. Dura Mater																
a. PHONE 212-779-1608 EXT _____		e. Embryo <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous																
b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____)		f. Fascia																
c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY		g. Heart Valve																
5. ENTER CORRECTIONS TO ITEM 4		h. Ligament																
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		i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous																
a. PHONE 310-443-5244 EXT 1172		j. Pericardium																
7. ENTER CORRECTIONS TO ITEM 6		k. Peripheral Blood Stem Cells <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic																
b. PHONE _____		l. Sclera																
8. U.S. AGENT		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							
a. E-MAIL _____		n. Skin																
9. REPORTING OFFICIAL'S SIGNATURE 		o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic																
a. TYPED NAME Rama Tyagi		p. Tendon																
b. E-MAIL rtyagi@cryobank.com		q. Umbilical Cord Blood Stem Cells <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic																
c. TITLE Director, Quality/Regulatory Affairs		r. Vascular Graft																
d. DATE 28-NOV-2011		s. Testicular Tissue		X			X	X	X	X	X							
		t.																
		u.																
		v.																