


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) <i>(See reverse side for instructions)</i>	1. REGISTRATION NUMBER (Field Establishment Identifier) FEI: 3003351041	2. REASON FOR SUBMISSION a. <input type="checkbox"/> INITIAL REGISTRATION / LISTING b. <input checked="" type="checkbox"/> ANNUAL REGISTRATION / LISTING c. <input type="checkbox"/> CHANGE IN INFORMATION d. <input type="checkbox"/> INACTIVE	1 VALIDATION—FOR FDA USE ONLY VALIDATED BY FDA:29-NOV-2011 DISTRICT: San Francisco 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													
	<i>Establishment Functions</i>													
	<i>Types of HCT / Ps</i>	Recover	Screen	Test	Package	Process	Store	Label	Distribute					
a. BLOOD FDA 2830 NO. _____ b. DEVICES FDA 2891 NO. _____ c. DRUG FDA 2656 NO. _____	a. Bone													
	b. Cartilage													
	c. Cornea													
	d. Dura Mater													
	e. Embryo <input checked="" type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous						X				X			
	f. Fascia													
4. PHYSICAL LOCATION <i>(Include legal name, number and street, city, state, country, and post office code)</i> 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	g. Heart Valve													
	h. Ligament													
	i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous													
	j. Pericardium													
	k. Peripheral Blood Stem Cells <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	X				
5. ENTER CORRECTIONS TO ITEM 4	n. Skin													
	o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic													
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 a. PHONE 310-443-5244 EXT 1172	p. Tendon													
	q. Umbilical Cord Blood Stem Cells <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic													
	r. Vascular Graft													
7. ENTER CORRECTIONS TO ITEM 6 b. PHONE _____	s.													
	t.													
	u.													
	v.													
8. U.S. AGENT 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 28-NOV-2011														