

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 (FDA Establishment Identifier) FEI: 3005342355	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	VALIDATION-FOR FDA USE ONLY VALIDATED BY FDA: 23-NOV-2016 DISTRICT: Los Angeles PRINTED BY FDA: 15-DEC-2016										
PART I - ESTABLISHMENT INFORMATION 3. OTHER FDA REGISTRATIONS a. BLOOD FDA 2830 NO. _____ b. DEVICES FDA 2891 NO. _____ c. DRUG FDA 2656 NO. _____		PART II - PRODUCT INFORMATION 10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps			11. HCT/PS DESCRIBED IN 21 CFR 127.110 12. HCT/PS AS MEDICAL DEVICES 13. HCT/PS AS DRUGS OR BIOLOGICAL DRUGS 14. PROPRIETARY NAME(S)									
4. PHYSICAL LOCATION (include legal name, number and street, city, state, country, and post office code) California Cryobank, LLC; California Cryobank Stem Cell Services, LLC (DBA "FamilyCord") 11915 La Grange Avenue Los Angeles, California 90025-5213 a. PHONE 310-443-5244 EXT 1185 b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY		Establishment Functions												
5. ENTER CORRECTIONS TO ITEM 4		Types of HCT / Ps	Recover	Screen	Test	Package	Process	Store	Label	Distribute	11. HCT/PS DESCRIBED IN 21 CFR 127.110	12. HCT/PS AS MEDICAL DEVICES	13. HCT/PS AS DRUGS OR BIOLOGICAL DRUGS	14. PROPRIETARY NAME(S)
6. MAILING ADDRESS OF REPORTING OFFICIAL (include institution name if applicable, number and street, city, state, country, and post office code) California Cryobank Attn: Joel Reynolds 11915 La Grange Avenue Los Angeles, California 90025-5213 a. PHONE 310-443-5244 EXT 1185		a. Bone												
7. ENTER CORRECTIONS TO ITEM 6 b. PHONE _____		b. Cartilage												
8. U.S. AGENT a. E-MAIL _____		c. Cornea												
9. REPORTING OFFICIAL'S SIGNATURE a. TYPED NAME Joel Reynolds b. E-MAIL jreynolds@cryobank.com c. TITLE Director, Quality and Regulatory Affairs d. DATE 22-NOV-2016		d. Dura Mater												
		e. Embryo						X		X	X			
		f. Fascia												
		g. Heart Valve												
		h. Ligament												
		i. Oocyte		X				X		X	X			
		j. Pericardium												
		k. Peripheral Blood Stem					X	X	X	X	X			
		l. Sclera												
		m. Semen	X	X		X	X	X	X	X	X			
		n. Skin												
		o. Somatic Cell Therapy Products						X					X	
		p. Tendon												
		q. Umbilical Cord Blood					X	X	X	X	X			
		r. Vascular Graft												
		s. Testicular Tissue		X			X	X	X	X	X			
		t. Umbilical Cord					X	X	X	X	X			
		u.												
		v.												