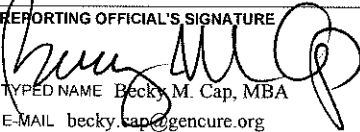


DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/Ps) (See reverse side for instructions)		1. REGISTRATION NUMBER (FDA Establishment Identifier) FEI: 3010041508	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:01-DEC-2017 DISTRICT: Dallas PRINTED BY FDA:27-JAN-2018									
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 a. BLOOD FDA 2830 NO. _____ b. DEVICES FDA 2891 NO. _____ c. DRUG FDA 2656 NO. _____		10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps											
4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code) Gencure Cord Blood Center GenCure 6211 IH-10 West San Antonio, Texas 78201 a. PHONE 210-731-5535 EXT _____ b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY		Types of HCT / Ps	Recover	Screen	Test	Package	Process	Store	Label	Distribute			
5. ENTER CORRECTIONS TO ITEM 4 6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code) Gencure Cord Blood Center Attn: Becky M. Cap, MBA GenCure 6211 IH-10 West San Antonio, Texas 78201 a. PHONE 210-731-5586 EXT _____		a. Bone											
		b. Cartilage											
		c. Cornea											
		d. Dura Mater											
		e. Embryo <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous											
		f. Fascia											
		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 <input checked="" type="checkbox"/> Autologous <input checked="" type="checkbox"/> Family Related <input checked="" type="checkbox"/> Allogeneic						X	X				X
		l. Sclera											
		m. Semen <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous											
		n. Skin											
7. ENTER CORRECTIONS TO ITEM 6		c. Somatic Cell Therapy Products <input checked="" type="checkbox"/> Autologous <input checked="" type="checkbox"/> Family Related <input checked="" type="checkbox"/> Allogeneic	X	X		X	X	X	X	X	X		
8. U.S. AGENT a. E-MAIL _____		p. Tendon											
		q. Umbilical Cord Blood <input checked="" type="checkbox"/> Autologous <input checked="" type="checkbox"/> Family Related <input checked="" type="checkbox"/> Allogeneic	X	X		X	X	X	X	X	X	X	
		r. Vascular Graft											
9. REPORTING OFFICIAL'S SIGNATURE  a. TYPED NAME Becky M. Cap, MBA b. E-MAIL becky.cap@gencure.org c. TITLE Chief Operating Officer		s. Placenta	X	X		X	X	X	X	X			
d. DATE 01-DEC-2017		t.											
		u.											
		v.											