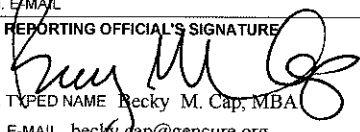


DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/PS) (See reverse side for instructions)		1. REGISTRATION NUMBER (FDA Establishment Identifier) FEI: 3011548632	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 OBSERVED IN 21 CFR 127.110	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 1221 E. 10th St. #103 Weslaco, Texas 78596 a. PHONE 2107315569 EXT _____ b. <input checked="" type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. 3010056221) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY		Types of HCT / Ps	Establishment Functions									
		Recover Screen Test Package Process Store Label Distribute										
5. ENTER CORRECTIONS TO ITEM 4		a. Bone	X				X			X		
		b. Cartilage	X				X			X		
6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code) GenCure Attn: Becky M. Cap, MBA 6211 IH 10 West San Antonio, Texas 78201 a. PHONE 210-731-5586 EXT _____		c. Cornea	X				X			X		
		d. Dura Mater										
7. ENTER CORRECTIONS TO ITEM 6		e. Embryo <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous										
		f. Fascia	X				X			X		
8. U.S. AGENT a. E-MAIL _____		g. Heart Valve	X				X			X		
		h. Ligament	X				X			X		
9. REPORTING OFFICIAL'S SIGNATURE  a. TYPED NAME Becky M. Cap, MBA b. E-MAIL becky_cap@gencure.org c. TITLE COO		i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous										
		j. Pericardium	X				X			X		
d. DATE 01-DEC-2017		k. Peripheral Blood Stem <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic										
		l. Sclera										
b. PHONE _____		m. Semen <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous										
		n. Skin	X				X			X		
c. TITLE COO		o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic										
		p. Tendon	X				X			X		
d. DATE 01-DEC-2017		q. Umbilical Cord Blood <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic										
		r. Vascular Graft	X				X			X		
d. DATE 01-DEC-2017		s. Nerve Tissue	X				X			X		
		t. Adipose Tissue	X				X			X		
d. DATE 01-DEC-2017		u.										
		v.										