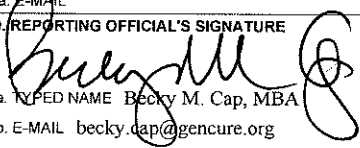


DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/PS) (See reverse side for instructions)		1. REGISTRATION NUMBER (FDA Establishment Identifier) FEI: 3010056221	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 Tissue Center 6211 IH-10 West San Antonio, Texas 78201 a. PHONE 210-731-5569 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	Establishment Functions										
5. ENTER CORRECTIONS TO ITEM 4		a. Bone	X	X		X	X	X	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 _____		b. Cartilage	X	X			X	X		X	X		
7. ENTER CORRECTIONS TO ITEM 6		c. Cornea	X	X							X		
b. PHONE _____		d. Dura Mater											
8. U.S. AGENT		e. Embryo <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous											
9. REPORTING OFFICIAL'S SIGNATURE  a. TYPED NAME Becky M. Cap, MBA b. E-MAIL becky.cap@gencure.org c. TITLE Chief Operating Officer		f. Fascia	X	X		X	X	X	X	X	X		
d. DATE 01-DEC-2017		g. Heart Valve	X	X				X		X	X		
		h. Ligament	X	X		X	X	X	X	X	X		
		i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous											
		j. Pericardium	X	X		X	X	X	X	X	X		
		k. Peripheral Blood Stem <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic											
		l. Sclera											
		m. Semen <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous											
		n. Skin	X	X			X				X		
		o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic											
		p. Tendon	X	X		X	X	X	X	X	X		
		q. Umbilical Cord Blood <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic											
		r. Vascular Graft	X	X				X		X	X		
		s. Nerve Tissue	X	X				X		X	X		
		t. Placenta		X		X	X	X	X	X	X		
		u. Adipose Tissue	X	X							X		
		v.											