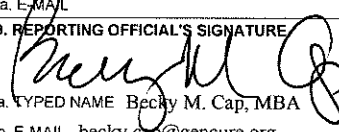


DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/PS) (See reverse side for instructions)		1. REGISTRATION NUMBER (FDA Establishment Identifier) FEI: 3010056215	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 1 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 Cellular Therapy Center 6211 IH10 West at First Park Ten Blvd. 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	Establishment Functions									
5. ENTER CORRECTIONS TO ITEM 4		a. Bone										
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 IH10 West at First Park Ten Blvd. San Antonio, Texas 78201 a. PHONE 210-731-5586 EXT _____		b. Cartilage										
7. ENTER CORRECTIONS TO ITEM 6		c. Cornea										
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 d. DATE 01-DEC-2017		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	X	X	X	X		X
		l. Sclera										
		m. Semen <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous										
		n. Skin										
		o. Somatic Cell Therapy Products <input checked="" type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic	X			X						X
		p. Tendon										
		q. Umbilical Cord Blood <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic										
		r. Vascular Graft										
		s. Therapeutic Cells	X	X		X	X	X	X	X	X	X
		t.										
		u.										
		v.										