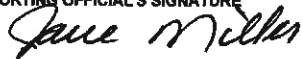


DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/Ps) (See reverse side for instructions)		1. REGISTRATION NUMBER (FDA Establishment Identifier) FEI: 0001046616	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:16-NOV-2016 DISTRICT: Atlanta PRINTED BY FDA:15-DEC-2016								
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. FEI: 0001046616 b. DEVICES FDA 2891 NO. _____ c. DRUG FDA 2856 NO. _____		10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps										
		Establishment Functions										
		Types of HCT / Ps	Recover	Screen	Test	Package	Process	Store			Label	Distribute
4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code) Walter L. Shepard Community Blood Center 1533 Wrightsboro Road Augusta, Georgia 30904 a. PHONE 706-737-4551 EXT _____ b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY		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										
5. ENTER CORRECTIONS TO ITEM 4		g. Heart Valve										
		h. Ligament										
		i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous										
6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code) Walter L. Shepard Community Blood Center Attn: Jane Miller, MBA,MT(ASCP) 1533 Wrightsboro Road Augusta, Georgia 30904 a. PHONE 706-737-4551 EXT _____		j. Pericardium										
		k. Peripheral Blood Stem <input checked="" type="checkbox"/> Autologous <input 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										
7. ENTER CORRECTIONS TO ITEM 6 a. PHONE _____ b. PHONE _____		n. Skin										
		o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic										
8. U.S. AGENT a. E-MAIL _____		p. Tendon										
		q. Umbilical Cord Blood <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic										
		r. Vascular Graft										
9. REPORTING OFFICIAL'S SIGNATURE  a. TYPED NAME Jane Miller, MBA,MT(ASCP) b. E-MAIL jmiller@shepardblood.org c. TITLE Director of Quality Assurance d. DATE 15-NOV-2016		s.										
		t.										
		u.										
		v.										