

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) <i>(See reverse side for instructions)</i>		1. REGISTRATION NUMBER (Field Establishment Identifier) FEI: 0001072542	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:05-JAN-2010 DISTRICT: Florida PRINTED BY FDA:25-JAN-2010								
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: 0001072542 b. DEVICES FDA 2891 NO. _____ c. DRUG FDA 2656 NO. _____		10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps										
4. PHYSICAL LOCATION <i>(Include legal name, number and street, city, state, country, and post office code)</i> FBS-Southeastern Community Blood Center, Inc. 1731 Riggins Road Tallahassee, Florida 32308 a. PHONE 850-877-7181 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		Recover	Screen	Test	Package	Process	Store	Label	Distribute			
6. MAILING ADDRESS OF REPORTING OFFICIAL <i>(Include institution name if applicable, number and street, city, state, country, and post office code)</i> Florida Blood Services, Inc. Attn: Judy B. Smith, D.M., MBA, MT(ASCP)S 10100 Dr. Martin Luther King Jr. St. N. St. Petersburg, Florida 33716-2500 a. PHONE 727-568-1176 EXT _____ b. PHONE _____		a. Bone					X		X	X		
		b. Cartilage										
		c. Cornea										
		d. Dura Mater										
		e. Embryo <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous										
		f. Fascia					X		X	X		
		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 Cells <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		
		o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic										
		p. Tendon					X		X	X		
		q. Umbilical Cord Blood Stem Cells <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic										
		r. Vascular Graft										
8. U.S. AGENT a. E-MAIL _____		s.										
		t.										
		u.										
		v.										
9. REPORTING OFFICIAL'S SIGNATURE a. TYPED NAME Judy B. Smith, D.M., MBA, MT(ASCP)S b. E-MAIL jsmith@fbsblood.org c. TITLE Director of Quality Assurance d. DATE 31-DEC-2009												