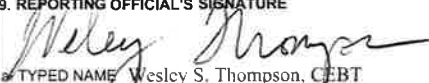


DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/PS) (See reverse side for instructions)		1. REGISTRATION NUMBER (FDA Establishment Identifier) FEI: 3000215034	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-DEC-2017 DISTRICT: New Orleans 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 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										
		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) Southern Eye Bank 2701 Kingman Street Suite 200 Metairie, Louisiana 70006		a. Bone										
		b. Cartilage										
		c. Cornea	X	X				X	X	X	X	X
		d. Dura Mater										
a. PHONE 504-891-3937 EXT _____ b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY		e. Embryo	<input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous									
5. ENTER CORRECTIONS TO ITEM 4		f. Fascia										
		g. Heart Valve										
		h. Ligament										
6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code) Southern Eye Bank Attn: Wesley S. Thompson, CEBT 2701 Kingman Street Suite 200 Metairie, Louisiana 70006		i. Oocyte	<input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous									
a. PHONE 504-891-3937 EXT 1004		j. Pericardium										
7. ENTER CORRECTIONS TO ITEM 6		k. Peripheral Blood Stem	<input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic									
b. PHONE _____		l. Sclera	X	X		X	X	X	X	X		
		m. Semen	<input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous									
8. U.S. AGENT		n. Skin										
		o. Somatic Cell Therapy Products	<input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic									
		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 Wesley S. Thompson, CEBT b. E-MAIL wthompson@southerneyebank.org c. TITLE Quality Assurance Director d. DATE 05-DEC-2017		s.										
		t.										
		u.										
		v.										