

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION <b>ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES,                  AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/Ps)</b> (See reverse side for instructions)		<b>1. REGISTRATION NUMBER</b> (FDA Establishment Identifier)  FEI: 3001238012	<b>2. REASON FOR SUBMISSION</b> a. <input type="checkbox"/> INITIAL REGISTRATION / LISTING b. <input type="checkbox"/> ANNUAL REGISTRATION / LISTING c. <input checked="" type="checkbox"/> CHANGE IN INFORMATION d. <input type="checkbox"/> INACTIVE	VALIDATION--FOR FDA USE ONLY VALIDATED BY FDA:16-DEC-2016 DISTRICT: Dallas PRINTED BY FDA:28-DEC-2016										
<b>PART I - ESTABLISHMENT INFORMATION</b>		<b>PART II - PRODUCT INFORMATION</b>							11. HCT/Ps DUS CPTD IN 21 CFR 1271.10	12. HCT/Ps REGULATED AS MEDICAL DEVICES	13. HCT/Ps REGULATED AS BIOLOGICAL DRUGS	<b>14. PROPRIETARY                  NAME(S)</b>		
<b>3. OTHER FDA REGISTRATIONS</b>  a. BLOOD FDA 2830 NO. _____  b. DEVICES FDA 2891 NO. _____  c. DRUG FDA 2656 NO. _____		<b>10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps</b>												
<b>4. PHYSICAL LOCATION</b> (Include legal name, number and street, city, state, country, and post office code) Lone Star Lions Eye Bank  102 E. Wheeler Manor, Texas 78653  a. PHONE 512-457-0638 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											
<b>5. ENTER CORRECTIONS TO ITEM 4</b>		a. Bone												
		b. Cartilage												
		c. Cornea	X	X		X	X	X	X	X	X			
		d. Dura Mater												
		e. Embryo												
		<input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous												
		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 type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic												
		l. Sclera	X	X		X	X	X	X	X	X			
		m. Semen												
		<input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous												
		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												
		s.												
		t.												
		u.												
		v.												
<b>9. REPORTING OFFICIAL'S SIGNATURE</b>  a. TYPED NAME Erica Garcia, CEBT b. E-MAIL egarcia@lsleb.org c. TITLE Director of QA/QC d. DATE 15-DEC-2016														