

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: 3010949709

2. REASON FOR SUBMISSION
 a. INITIAL REGISTRATION / LISTING
 b. ANNUAL REGISTRATION / LISTING
 c. CHANGE IN INFORMATION
 d. INACTIVE

VALIDATION—FOR FDA USE ONLY
 VALIDATED BY FDA: 18-NOV-2014
 DISTRICT: New Orleans
 PRINTED BY FDA: 04-DEC-2014

PART I - ESTABLISHMENT INFORMATION		PART II - PRODUCT INFORMATION										11. ACTIVE OR EXPIRED ON 12/31/13	12. HCT/Ps REGULATED AS MEDICAL DEVICES	13. HCT/Ps REGULATED AS DRUGS OR BIOLOGICAL DRUGS	14. PROPRIETARY NAME(S)		
3. OTHER FDA REGISTRATIONS		10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps															
		Types of HCT / Ps	Establishment Functions							Recover	Screen	Test	Package	Process	Store	Label	Distribute
			Recover	Screen	Test	Package	Process	Store	Label								
4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code) East Tennessee Lions Eye Bank 201 W. Watauga Ave. Johnson City, Tennessee 37602		a. Bone															
		b. Cartilage															
		c. Cornea	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	
		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.															

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1. REGISTRATION NUMBER
 (FDA Establishment Identifier)
 FEI: 3002689373

2. REASON FOR SUBMISSION
 a. INITIAL REGISTRATION / LISTING
 b. ANNUAL REGISTRATION / LISTING
 c. CHANGE IN INFORMATION
 d. INACTIVE

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See Instructions for OMB Statement FORM APPROVED OMB No. 0910-0043, Expiration Date: 3/31/2017

PART I - ESTABLISHMENT INFORMATION		PART II - PRODUCT INFORMATION									
3. OTHER FDA REGISTRATIONS		10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps									
a. BLOOD FDA 2830 NO. _____		Types of HCT / Ps									
b. DEVICES FDA 2891 NO. _____		Establishment Functions									
c. DRUG FDA 2856 NO. _____		Recover	Screen	Test	Package	Process	Store	Label	Distribute	11. HCT/Ps 12. HCT/Ps 13. HCT/Ps 14. PROPRIETARY NAMES	
4. PHYSICAL LOCATION (include legal name, number and street city, state, country, and post office code) East Tennessee Lions Eye Bank 1924 Alcoa Hwy, Ste U-26 Knoxville, Tennessee 37920		a. Bone									
5. MAILING ADDRESS OF REPORTING OFFICIAL (include institution name if applicable, number and street, city, state, country, and post office code) East Tennessee Lions Eye Bank Attn: Yvette Venters 1924 Alcoa Hwy, Ste U-26 Knoxville, Tennessee 37920		b. Cartilage									
6. PHONE 865-305-9625 EXT _____		c. Cornea	X	X		X	X	X	X	X	
7. ENTER CORRECTIONS TO ITEM 6		d. Dura Mater									
8. U.S. AGENT		e. Embryo									
9. REPORTING OFFICIAL'S SIGNATURE		f. Fissile									
a. TYPED NAME Yvette Venters		g. Heart Valve									
b. EMAIL yventers@uttnk.edu		h. Ligament									
c. TITLE QA Director		i. Oocyte									
d. DATE 17-NOV-2014		j. Pericardium									
		k. Peritoneal Blood Stem									
		l. Sclera	X				X	X	X	X	
		m. Semen									
		n. Skin									
		o. Somatic Cell Therapy Products									
		p. Tendon									
		q. Umbilical Cord Blood									
		r. Vascular Graft									
		s. _____									
		t. _____									
		u. _____									
		v. _____									