

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: 3000718793	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:19-NOV-2011 DISTRICT: Cincinnati PRINTED BY FDA:23-NOV-2011
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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	10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps															
a. BLOOD FDA 2830 NO. _____ b. DEVICES FDA 2891 NO. _____ c. DRUG FDA 2656 NO. _____	Types of HCT / Ps	Establishment Functions														
4. PHYSICAL LOCATION <i>(Include legal name, number and street, city, state, country, and post office code)</i> University of Louisville Lions Eye Bank 301 E. Muhammad Ali Blvd Louisville, Kentucky 40202 a. PHONE 502-852-5457 EXT _____ b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY		Recover	Screen	Test	Package	Process	Store	Label	Distribute							
5. ENTER CORRECTIONS TO ITEM 4	a. Bone															
	b. Cartilage															
	c. Cornea	X	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 Cells <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic															
	l. Sclera							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 Stem Cells <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic															
	r. Vascular Graft															
	s.															
	t.															
	u.															
	v.															
6. MAILING ADDRESS OF REPORTING OFFICIAL <i>(Include institution name if applicable, number and street, city, state, country, and post office code)</i> University of Louisville Lions Eye Bank Attn: Joseph R. Bille, CEBT, CTBS 301 E. Muhammad Ali Blvd Louisville, Kentucky 40202 a. PHONE 502-852-5457 EXT _____																
7. ENTER CORRECTIONS TO ITEM 6	b. PHONE															
8. U.S. AGENT	a. E-MAIL															
9. REPORTING OFFICIAL'S SIGNATURE	a. TYPED NAME Joseph R. Bille, CEBT, CTBS b. E-MAIL jrbill01@louisville.edu c. TITLE Director d. DATE 18-NOV-2011															