

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> <i>(See reverse side for instructions)</i>	<b>1. REGISTRATION NUMBER</b> (Field Establishment Identifier)  FEI: 0001570984	<b>2. REASON FOR SUBMISSION</b> 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	<b>VALIDATION--FOR FDA USE ONLY</b> VALIDATED BY FDA:29-DEC-2010 DISTRICT: Cincinnati PRINTED BY FDA:05-JAN-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																					
	Types of HCT / Ps	Establishment Functions								Recover					Screen	Test	Package	Process	Store	Label	Distribute	
a. BLOOD FDA 2830 NO. FEI: 0001570984  b. DEVICES FDA 2891 NO. _____  c. DRUG FDA 2656 NO. _____		a. Bone	X	X	X	X	X	X	X		X	X	X									
4. PHYSICAL LOCATION <i>(Include legal name, number and street, city, state, country, and post office code)</i> Community Blood Center dba Community Tissue Services 349 S. Main Street Dayton, Ohio 45402-2715  a. PHONE 937-461-3450 EXT 3610 b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY	b. Cartilage	X	X	X	X	X	X	X	X	X												
	c. Cornea			X														X				
	d. Dura Mater																					
	e. Embryo <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous																					
	f. Fascia	X	X	X	X	X	X	X	X	X	X											
5. ENTER CORRECTIONS TO ITEM 4	g. Heart Valve	X	X	X														X				
	h. Ligament	X	X	X	X	X	X	X	X	X												
	i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous																					
6. MAILING ADDRESS OF REPORTING OFFICIAL <i>(Include institution name if applicable, number and street, city, state, country, and post office code)</i> Community Blood Center dba Community Tissue Services Attn: David M. Smith, MD 349 S. Main Street Dayton, Ohio 45402-2715  a. PHONE 937-461-3450 EXT 3610	j. Pericardium	X	X	X	X	X	X	X	X	X												
	k. Peripheral Blood Stem Cells <input checked="" type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic	X	X	X	X	X	X	X	X	X	X											
	l. Sclera			X															X			
	m. Semen <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous																					
7. ENTER CORRECTIONS TO ITEM 6 b. PHONE	n. Skin	X	X	X	X	X	X	X	X	X												
	o. Somatic Cell Therapy Products <input checked="" type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic	X				X														X		
8. U.S. AGENT	p. Tendon	X	X	X	X	X	X	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	X	X	X															X			
9. REPORTING OFFICIAL'S SIGNATURE	s. Parathyroid					X	X			X	X											
	t. Peritoneal Membrane	X	X	X	X	X	X	X	X	X												
	u.																					
	v.																					