

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: 0001876867	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:08-DEC-2011 DISTRICT: Detroit PRINTED BY FDA:15-DEC-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 a. BLOOD FDA 2830 NO. FEI: 0001876867 b. DEVICES FDA 2891 NO. _____ c. DRUG FDA 2656 NO. _____	10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps <table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th rowspan="2">Types of HCT / Ps</th> <th colspan="8">Establishment Functions</th> <th rowspan="2">11. HCT/PS DESCRIBED IN 21 CFR 1271.10</th> <th rowspan="2">12. HCT/PS REGULATED AS MEDICAL DEVICES</th> <th rowspan="2">13. HCT/PS REGULATED AS DRUGS OR BIOLOGICAL DRUGS</th> <th rowspan="2">14. PROPRIETARY NAME(S)</th> </tr> <tr> <th>Recover</th> <th>Screen</th> <th>Test</th> <th>Package</th> <th>Process</th> <th>Store</th> <th>Label</th> <th>Distribute</th> </tr> </thead> </table>	Types of HCT / Ps	Establishment Functions								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)	Recover	Screen	Test	Package	Process	Store	Label	Distribute				
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4. PHYSICAL LOCATION <i>(Include legal name, number and street, city, state, country, and post office code)</i> Community Blood Center 4450 Garwood Place Richmond, Indiana 47374 a. PHONE 765-962-6329 EXT _____ b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY	a. Bone																									
	b. Cartilage																									
	c. Cornea																									
	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																									
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 Attn: David M. Smith, MD 349 S. Main Street Dayton, Ohio 45402-2715 a. PHONE 937-461-3450 EXT 3610	k. Peripheral Blood Stem Cells <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic																									
	l. Sclera																									
	m. Semen <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous																									
	n. Skin																									
7. ENTER CORRECTIONS TO ITEM 6 b. PHONE _____	o. Somatic Cell Therapy Products <input checked="" type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic	X			X						X															
	p. Tendon																									
8. U.S. AGENT a. E-MAIL _____	q. Umbilical Cord Blood Stem Cells <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic																									
	r. Vascular Graft																									
9. REPORTING OFFICIAL'S SIGNATURE a. TYPED NAME David M. Smith, MD b. E-MAIL dsmith@cbccts.org c. TITLE CEO d. DATE 07-DEC-2011	s.																									
	t.																									
	u.																									
	v.																									