

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 (Field Establishment Identifier) FEI: 3008808182	2. REASON FOR SUBMISSION a. <input checked="" type="checkbox"/> INITIAL REGISTRATION / LISTING b. <input 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:02-MAR-2011 DISTRICT: Cincinnati PRINTED BY FDA:02-MAR-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. _____ b. DEVICES FDA 2891 NO. _____ c. DRUG FDA 2656 NO. _____		a. Bone					X	X	X		X	X	X								
4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code) Community Blood Center dba Community Tissue Services 2900 College Drive Kettering, Ohio 45420 a. PHONE 937-222-0228 EXT _____ 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										
	c. Cornea																				
	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									
5. ENTER CORRECTIONS TO ITEM 4	g. Heart Valve																				
	h. Ligament					X	X	X	X	X	X										
	i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous																				
	j. Pericardium					X	X	X	X	X	X										
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6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code) Community Blood Center dba Community Tissue Services Attn: David M. Smith, MD 349 South Main Street Dayton, Ohio 45402-2715 a. PHONE 937-461-3450 EXT 3610	l. Sclera																				
	m. Semen <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous																				
	n. Skin					X	X	X	X	X	X										
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	p. Tendon					X	X	X	X	X	X										
7. ENTER CORRECTIONS TO ITEM 6 b. PHONE _____	q. Umbilical Cord Blood <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic																				
	r. Vascular Graft																				
	s. Parathyroid							X	X		X	X									
	t. Peritoneal Membrane					X	X	X	X	X	X										
	u.																				
8. U.S. AGENT a. E-MAIL _____	v.																				
	9. REPORTING OFFICIAL'S SIGNATURE a. TYPED NAME David M. Smith, MD b. E-MAIL dsmith@cbccts.org c. TITLE CEO d. DATE 14-FEB-2011																				

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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: 3008808182	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-2013 DISTRICT: Cincinnati PRINTED BY FDA:09-DEC-2013
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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
a. BLOOD FDA 2830 NO. _____ b. DEVICES FDA 2891 NO. _____ c. DRUG FDA 2656 NO. _____		a. Bone				X	X	X	X		X	X							
4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code) Community Blood Center dba Community Tissue Services 2900 College Drive Kettering, Ohio 45420 a. PHONE 937-222-0228 EXT _____ 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									
	c. Cornea																		
	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								
	g. Heart Valve																		
	h. Ligament					X	X	X	X	X	X								
	i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous																		
	j. Pericardium					X	X	X	X	X	X								
	k. Peripheral Blood Stem <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																			
5. ENTER CORRECTIONS TO ITEM 4 6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code) Community Blood Center dba Community Tissue Services Attn: David M. Smith, MD 349 South Main Street Dayton, Ohio 45402-2715 a. PHONE 937-461-3450 EXT 3610	n. Skin				X	X	X	X	X	X									Dermapure
	o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic																		
7. ENTER CORRECTIONS TO ITEM 6 b. PHONE _____	p. Tendon				X	X	X	X	X	X									
	q. Umbilical Cord Blood <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic																		
	r. Vascular Graft																		
8. U.S. AGENT a. E-MAIL _____	s. Parathyroid					X	X		X	X									
	t. Peritoneal Membrane				X	X	X	X	X	X									Allomem
	u.																		
	v.																		
9. REPORTING OFFICIAL'S SIGNATURE a. TYPED NAME David M. Smith, MD b. E-MAIL dsmith@cbccts.org c. TITLE CEO d. DATE 18-NOV-2013																			

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: 3008808182	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:02-DEC-2014 DISTRICT: Cincinnati PRINTED BY FDA:22-DEC-2014
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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
a. BLOOD FDA 2830 NO. _____ b. DEVICES FDA 2891 NO. _____ c. DRUG FDA 2656 NO. _____		a. Bone					X	X	X		X	X	X							
4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code) Community Blood Center dba Community Tissue Services 2900 College Drive Kettering, Ohio 45420 a. PHONE 937-222-0228 EXT _____ 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									
	c. Cornea																			
	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									
	g. Heart Valve																			
	h. Ligament					X	X	X	X	X	X									
	i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous																			
	j. Pericardium					X	X	X	X	X	X									
	k. Peripheral Blood Stem <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																				
5. ENTER CORRECTIONS TO ITEM 4 6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code) Community Blood Center dba Community Tissue Services Attn: David M. Smith, MD 349 South Main Street Dayton, Ohio 45402-2715 a. PHONE 937-461-3450 EXT 3610	n. Skin					X	X	X	X	X	X								Dermapure	
	o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic																			
7. ENTER CORRECTIONS TO ITEM 6 b. PHONE _____ 8. U.S. AGENT a. E-MAIL _____	p. Tendon					X	X	X	X	X	X									
	q. Umbilical Cord Blood <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 01-DEC-2014	s. Parathyroid						X	X		X	X									
	t. Peritoneal Membrane					X	X	X	X	X	X								Allomem	
	u.																			
	v.																			

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: 3008808182	2. REASON FOR SUBMISSION 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:14-APR-2015 DISTRICT: Cincinnati PRINTED BY FDA:22-JUN-2015
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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				
4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code) Community Blood Center dba Community Tissue Services 2900 College Drive Kettering, Ohio 45420 a. PHONE 937-222-0228 EXT _____ b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY	a. Bone				X	X	X	X	X	X			*** See full text on next page
	b. Cartilage				X	X	X	X	X	X			
	c. Cornea												
	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			
	g. Heart Valve												
	h. Ligament				X	X	X	X	X	X			
	i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous												
	j. Pericardium				X	X	X	X	X	X			
k. Peripheral Blood Stem <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													
5. ENTER CORRECTIONS TO ITEM 4 6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code) Community Blood Center dba Community Tissue Services Attn: David M. Smith, MD 349 South Main Street Dayton, Ohio 45402-2715 a. PHONE 937-461-3450 EXT 3610	n. Skin				X	X	X	X	X	X			Dermapure
	o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic												
7. ENTER CORRECTIONS TO ITEM 6 b. PHONE _____	p. Tendon				X	X	X	X	X	X			
	q. Umbilical Cord Blood <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic												
	r. Vascular Graft												
8. U.S. AGENT a. E-MAIL _____	s. Parathyroid						X		X	X			
	t. Peritoneal Membrane				X	X	X	X	X	X			Allomem
	u.												
	v.												
9. REPORTING OFFICIAL'S SIGNATURE a. TYPED NAME David M. Smith, MD b. E-MAIL dsmith@cbccts.org c. TITLE CEO d. DATE 13-APR-2015													

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: 3008808182	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:17-NOV-2015 DISTRICT: Cincinnati PRINTED BY FDA:03-DEC-2015
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PART I - ESTABLISHMENT INFORMATION	PART II - PRODUCT INFORMATION														14. PROPRIETARY NAME(S)	
3. OTHER FDA REGISTRATIONS	10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps									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				
	Establishment Functions															
	Types of HCT / Ps	Recover	Screen	Test	Package	Process	Store	Label	Distribute							
4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code) Community Blood Center dba Community Tissue Services 2900 College Drive Kettering, Ohio 45420 a. PHONE 937-222-0228 EXT _____ b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY	a. Bone				X	X	X	X	X	X					*** See full text on next page	
	b. Cartilage				X	X	X	X	X	X						
	c. Cornea															
	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						
	g. Heart Valve															
	h. Ligament				X	X	X	X	X	X						
	i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous															
	j. Pericardium				X	X	X	X	X	X						
5. ENTER CORRECTIONS TO ITEM 4 6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code) Community Blood Center dba Community Tissue Services Attn: David M. Smith, MD 349 South Main Street Dayton, Ohio 45402-2715 a. PHONE 937-461-3450 EXT 3610	k. Peripheral Blood Stem <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				X	X	X	X	X	X					Dermapure, TruSkin	
	o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic															
	p. Tendon				X	X	X	X	X	X						
	q. Umbilical Cord Blood <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic															
	r. Vascular Graft															
	s. Parathyroid							X		X	X					
	t. Peritoneal Membrane				X	X	X	X	X	X					Allomem	
7. ENTER CORRECTIONS TO ITEM 6 b. PHONE _____	u.															
	v.															
8. U.S. AGENT a. E-MAIL _____																
9. REPORTING OFFICIAL'S SIGNATURE a. TYPED NAME David M. Smith, MD b. E-MAIL dsmith@cbccts.org c. TITLE CEO d. DATE 16-NOV-2015																