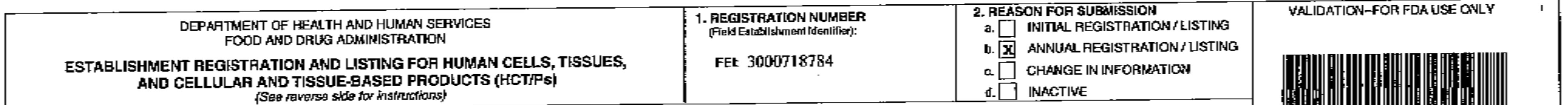
See Reverse for OMB Statement
FORM APPROVED: OMB No. 0910-0469. Expiration Date: July 31, 2007



DEPARTMENT OF HEALTH AND HUMAN SERVICES
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: 3000718784

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

VALIDATION–FOR FDA USE ONLY

VALIDATED BY FDA: 12-DEC-2005
PRINTED BY FDA: 12-DEC-2005
DISTRICT OFFICE: Cincinnati

PART I - ESTABLISHMENT INFORMATION

3. OTHER FDA REGISTRATIONS
- a. BLOOD FDA 2830 NO.
- b. DEVICES FDA 2891 NO.
- c. DRUG FDA 2656 NO.

4. PHYSICAL LOCATION *(Include legal name, number and street, city, state, country, and post office code)*

Community Blood Center dba Community Tissue Services
2736 N. Holland-Sylvania Road
Toledo, Ohio 43615

PHONE 419-536-4924 EXT

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/Community Tissue Services
349 South Main Street
Dayton, Ohio 45402-2715

PHONE 937-461-3450 EXT 3288

7. ENTER CORRECTIONS TO ITEM 6

8. U.S. AGENT

a. E-MAIL b. PHONE

9. REPORTING OFFICIAL'S SIGNATURE

a. TYPED NAME Judith E. Woll, MD
b. E-MAIL jwoll@cbccts.org
c. TITLE CEO d. DATE 29-NOV-2005

PART II - PRODUCT INFORMATION

10. ESTABLISHMENT FUNCTIONS:
- a [X] RECOVER
- b [X] SCREEN
- c [ ] TEST
- d [ ] PACKAGE
- e [ ] PROCESS
- f [X] STORE
- g [X] LABEL
- h [X] DISTRIBUTE

	TYPES OF HCT/Ps	11. HCT/Ps DESCRIBED IN 21 CFR 1271.10	12. HCT/Ps REGULATED AS MEDICAL DEVICES, DRUGS, OR BIOLOGICAL DRUGS	13. PROPRIETARY NAME(S)
a.	Bone	X		
b.	Cartilage	X		
c.	Cornea	X		
d.	Dura Mater			
e.	Embryo			
f.	Fascia	X		
g.	Heart Valve	X		
h.	Ligament	X		
i.	Oocyte			
j.	Pericardium	X		
k.	Peripheral Blood Stem Cells			
l.	Sclera	X		
m.	Semen			
n.	Skin	X		
o.	Somatic Cells			
p.	Tendon	X		
q.	Umbilical Cord Blood Stem Cells			
r.	Vascular Graft	X		
s.				
t.				
u.				
v.				

FORM FDA 3356 (8/04) PREVIOUS EDITION IS OBSOLETE.

See Reverse for OMB Statement
FORM APPROVED: OMB No. 0910-0469. Expiration Date: July 31, 2007

DEPARTMENT OF HEALTH AND HUMAN SERVICES
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: 3000718784

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

VALIDATION--FOR FDA USE ONLY 1

3000718784

VALIDATED BY FDA: 12-JAN-2007
PRINTED BY FDA: 02-FEB-2007
DISTRICT OFFICE: Cincinnati

PART I - ESTABLISHMENT INFORMATION

3. OTHER FDA REGISTRATIONS
- a. BLOOD FDA 2830 NO.
- b. DEVICES FDA 2891 NO.
- c. DRUG FDA 2656 NO.

4. PHYSICAL LOCATION *(Include legal name, number and street, city, state, country, and post office code)*

Community Blood Center dba Community Tissue Services
2736 N. Holland-Sylvania Road
Toledo, Ohio 43615

PHONE 419-536-4924 EXT

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: Judith E. Woll, MD
349 South Main Street
Dayton, Ohio 45402-2715

PHONE 937-461-3261 EXT

7. ENTER CORRECTIONS TO ITEM 6

8. U.S. AGENT

a. E-MAIL b. PHONE

9. REPORTING OFFICIAL'S SIGNATURE

a. TYPED NAME Judith E. Woll, MD
b. E-MAIL jwoll@cbccts.org
c. TITLE CEO d. DATE 01-DEC-2006

PART II - PRODUCT INFORMATION

10. ESTABLISHMENT FUNCTIONS:
- a [X] RECOVER
- b [X] SCREEN
- c [ ] TEST
- d [ ] PACKAGE
- e [ ] PROCESS
- f [X] STORE
- g [X] LABEL
- h [X] DISTRIBUTE

	TYPES OF HCT/Ps	11. HCT/Ps DESCRIBED IN 21 CFR 1271.10	12. HCT/Ps REGULATED AS MEDICAL DEVICES, DRUGS, OR BIOLOGICAL DRUGS	13. PROPRIETARY NAME(S)
a.	Bone	X		
b.	Cartilage	X		
c.	Cornea	X		
d.	Dura Mater			
e.	Embryo			
f.	Fascia	X		
g.	Heart Valve	X		
h.	Ligament	X		
i.	Oocyte			
j.	Pericardium	X		
k.	Peripheral Blood Stem Cells			
l.	Sclera	X		
m.	Semen			
n.	Skin	X		
o.	Somatic Cells			
p.	Tendon	X		
q.	Umbilical Cord Blood Stem Cells			
r.	Vascular Graft	X		
s.				
t.				
u.				
v.				

See Instructions for OMB Statement FORM APPROVED: OMB No. 0910-0543. Expiration Date: 7/31/10

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: 3000718784

2. REASON FOR SUBMISSION

- a. ☐ INITIAL REGISTRATION / LISTING
- b. ☒ ANNUAL REGISTRATION / LISTING
- c. ☐ CHANGE IN INFORMATION
- d. ☐ INACTIVE

VALIDATION--FOR FDA USE ONLY 1

3000718784

VALIDATED By FDA: 12/10/07 **PRINTED By FDA:** 12/17/07

DISTRICT: Cincinnati

PART I - ESTABLISHMENT INFORMATION

3. OTHER FDA REGISTRATIONS

- a. BLOOD FDA 2830 NO. ____
- b. DEVICES FDA 2891 NO. ____
- c. DRUG FDA 2656 NO. ____

4. PHYSICAL LOCATION *(Include legal name, number and street, city, state, country, and post office code)*

Community Blood Center dba Community Tissue Services"
2736 N. Holland-Sylvania Road
Toledo, Ohio 43615

a. PHONE 419-536-4924 EXT

b. ☐ SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO.____)

c. ☐ TESTING FOR MICRO-ORGANISMS ONLY

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

7. ENTER CORRECTIONS TO ITEM 6 b. PHONE

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/Medical Director d. DATE 05-DEC-2007

PART II - PRODUCT INFORMATION

10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps

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				
No HCT / P Specified												
a. Bone	X	X				X	X	X	X			
b. Cartilage	X	X				X	X	X	X			
c. Cornea	X	X							X			
d. Dura Mater												
e. Embryo ☐ SIP ☐ Directed ☐ Anonymous												
f. Fascia	X	X				X	X	X	X			
g. Heart Valve	X	X							X			
h. Ligament	X	X				X	X	X	X			
i. Oocyte ☐ SIP ☐ Directed ☐ Anonymous												
j. Pericardium	X	X							X			
k. Peripheral Blood Stem Cells ☐ Autologous ☐ Family Related ☐ Allogeneic												
l. Sclera	X	X							X			
m. Semen ☐ SIP ☐ Directed ☐ Anonymous												
n. Skin	X	X				X	X	X	X			
o. Somatic Cells ☐ Autologous ☐ Family Related ☐ Allogeneic												
p. Tendon	X	X				X	X	X	X			
q. Umbilical Cord Blood Stem Cells ☐ Autologous ☐ Family Related ☐ Allogeneic												
r. Vascular Graft	X	X							X			
s.												
t.												
u.												
v.												

See Instructions for OMB Statement FORM APPROVED: OMB No. 0910-0543. Expiration Date: 7/31/10

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: 3000718784

2. REASON FOR SUBMISSION

a. ☐ INITIAL REGISTRATION / LISTING
b. ☐ ANNUAL REGISTRATION / LISTING
c. ☒ CHANGE IN INFORMATION
d. ☐ INACTIVE

VALIDATION--FOR FDA USE ONLY 1
VALIDATED BY FDA:27-MAR-2008
DISTRICT: Cincinnati
PRINTED BY FDA:27-MAR-2008

PART I - ESTABLISHMENT INFORMATION

3. OTHER FDA REGISTRATIONS

a. BLOOD FDA 2830 NO.
b. DEVICES FDA 2891 NO.
c. DRUG FDA 2656 NO.

4. PHYSICAL LOCATION *(Include legal name, number and street, city, state, country, and post office code)*

Community Blood Center dba Community Tissue Services
2736 N. Holland-Sylvania Road
Toledo, Ohio 43615

a. PHONE 419-536-4924 EXT
b. ☐ SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO.________________
c. ☐ TESTING FOR MICRO-ORGANISMS ONLY

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

7. ENTER CORRECTIONS TO ITEM 6 b. PHONE

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/Medical Director d. DATE 20-MAR-2008

PART II - PRODUCT INFORMATION

10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps

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				
No HCT / P Specified												
a. Bone	X	X				X	X	X	X			
b. Cartilage	X	X				X	X	X	X			
c. Cornea	X	X							X			
d. Dura Mater												
e. Embryo ☐ SIP ☐ Directed ☐ Anonymous												
f. Fascia	X	X				X	X	X	X			
g. Heart Valve	X	X							X			
h. Ligament	X	X				X	X	X	X			
i. Oocyte ☐ SIP ☐ Directed ☐ Anonymous												
j. Pericardium	X	X				X	X	X	X			
k. Peripheral Blood Stem Cells ☐ Autologous ☐ Family Related ☐ Allogeneic												
l. Sclera	X	X							X			
m. Semen ☐ SIP ☐ Directed ☐ Anonymous												
n. Skin	X	X				X	X	X	X			
o. Somatic Cells ☐ Autologous ☐ Family Related ☐ Allogeneic												
p. Tendon	X	X				X	X	X	X			
q. Umbilical Cord Blood Stem Cells ☐ Autologous ☐ Family Related ☐ Allogeneic												
r. Vascular Graft	X	X							X			
s.												
t.												
u.												
v.												

FORM FDA 3356 (9/07) PREVIOUS EDITION IS OBSOLETE.

See Instructions for OMB Statement FORM APPROVED: OMB No. 0910-0543. Expiration Date: 8/31/10

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: 3000718784

2. REASON FOR SUBMISSION

a. ☐ INITIAL REGISTRATION / LISTING
b. ☒ ANNUAL REGISTRATION / LISTING
c. ☐ CHANGE IN INFORMATION
d. ☐ INACTIVE

VALIDATION--FOR FDA USE ONLY 1
VALIDATED BY FDA:30-DEC-2008
DISTRICT: Cincinnati
PRINTED BY FDA:05-JAN-2009

PART I - ESTABLISHMENT INFORMATION

3. OTHER FDA REGISTRATIONS

a. BLOOD FDA 2830 NO.
b. DEVICES FDA 2891 NO.
c. DRUG FDA 2656 NO.

4. PHYSICAL LOCATION *(Include legal name, number and street, city, state, country, and post office code)*

Community Blood Center dba Community Tissue Services
2736 N. Holland-Sylvania Road
Toledo, Ohio 43615

a. PHONE 419-536-4924 EXT
b. ☐ SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO.__________
c. ☐ TESTING FOR MICRO-ORGANISMS ONLY

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

7. ENTER CORRECTIONS TO ITEM 6 b. PHONE

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/Medical Director d. DATE 08-DEC-2008

PART II - PRODUCT INFORMATION

10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps

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				
a. Bone	X	X				X	X	X	X			
b. Cartilage	X	X				X	X	X	X			
c. Cornea	X	X							X			
d. Dura Mater												
e. Embryo ☐ SIP ☐ Directed ☐ Anonymous												
f. Fascia	X	X				X	X	X	X			
g. Heart Valve	X	X							X			
h. Ligament	X	X				X	X	X	X			
i. Oocyte ☐ SIP ☐ Directed ☐ Anonymous												
j. Pericardium	X	X				X	X	X	X			
k. Peripheral Blood Stem Cells ☐ Autologous ☐ Family Related ☐ Allogeneic												
l. Sclera	X	X							X			
m. Semen ☐ SIP ☐ Directed ☐ Anonymous												
n. Skin	X	X				X	X	X	X			
o. Somatic Cell Therapy Products ☐ Autologous ☐ Family Related ☐ Allogeneic												
p. Tendon	X	X				X	X	X	X			
q. Umbilical Cord Blood Stem Cells ☐ Autologous ☐ Family Related ☐ Allogeneic												
r. Vascular Graft	X	X							X			
s. Parathyroid						X		X	X			
t. Peritoneal Membrane	X	X				X	X	X	X			
u.												
v.												

See Instructions for OMB Statement FORM APPROVED: OMB No. 0910-0543. Expiration Date: 8/31/10

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: 3000718784

2. REASON FOR SUBMISSION

a. ☐ INITIAL REGISTRATION / LISTING
b. ☒ ANNUAL REGISTRATION / LISTING
c. ☐ CHANGE IN INFORMATION
d. ☐ INACTIVE

VALIDATION--FOR FDA USE ONLY 1
VALIDATED BY FDA:05-JAN-2010
DISTRICT: Cincinnati
PRINTED BY FDA:23-FEB-2010

PART I - ESTABLISHMENT INFORMATION

3. OTHER FDA REGISTRATIONS

a. BLOOD FDA 2830 NO. __________

b. DEVICES FDA 2891 NO. __________

c. DRUG FDA 2656 NO. __________

4. PHYSICAL LOCATION *(Include legal name, number and street, city, state, country, and post office code)*

Community Blood Center dba Community Tissue Services
2736 N. Holland-Sylvania Road
Toledo, Ohio 43615

a. PHONE 419-536-4924 EXT

b. ☐ SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO.__________)

c. ☐ TESTING FOR MICRO-ORGANISMS ONLY

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

7. ENTER CORRECTIONS TO ITEM 6 b. PHONE

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 29-DEC-2009

PART II - PRODUCT INFORMATION

10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps

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				
a. Bone	X	X				X		X	X			
b. Cartilage	X	X				X		X	X			
c. Cornea	X	X							X			
d. Dura Mater												
e. Embryo ☐ SIP ☐ Directed ☐ Anonymous												
f. Fascia	X	X				X		X	X			
g. Heart Valve	X	X							X			
h. Ligament	X	X				X		X	X			
i. Oocyte ☐ SIP ☐ Directed ☐ Anonymous												
j. Pericardium	X	X				X		X	X			
k. Peripheral Blood Stem Cells ☐ Autologous ☐ Family Related ☐ Allogeneic												
l. Sclera	X	X							X			
m. Semen ☐ SIP ☐ Directed ☐ Anonymous												
n. Skin	X	X				X		X	X			
o. Somatic Cell Therapy Products ☐ Autologous ☐ Family Related ☐ Allogeneic												
p. Tendon	X	X				X		X	X			
q. Umbilical Cord Blood Stem Cells ☐ Autologous ☐ Family Related ☐ Allogeneic												
r. Vascular Graft	X	X							X			
s. Peritoneal Membrane	X	X				X		X	X			
t.												
u.												
v.												

See Instructions for OMB Statement FORM APPROVED: OMB No. 0910-0543. Expiration Date: 8/31/10

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: 3000718784

2. REASON FOR SUBMISSION

a. ☐ INITIAL REGISTRATION / LISTING
b. ☒ ANNUAL REGISTRATION / LISTING
c. ☐ CHANGE IN INFORMATION
d. ☐ INACTIVE

VALIDATION--FOR FDA USE ONLY 1
VALIDATED BY FDA:29-DEC-2010
DISTRICT: Cincinnati
PRINTED BY FDA:05-JAN-2011

PART I - ESTABLISHMENT INFORMATION

3. OTHER FDA REGISTRATIONS

a. BLOOD FDA 2830 NO.
b. DEVICES FDA 2891 NO.
c. DRUG FDA 2656 NO.

4. PHYSICAL LOCATION *(Include legal name, number and street, city, state, country, and post office code)*

Community Blood Center dba Community Tissue Services
2736 N. Holland-Sylvania Road
Toledo, Ohio 43615

a. PHONE 419-536-4924 EXT
b. ☐ SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO.__________)
c. ☐ TESTING FOR MICRO-ORGANISMS ONLY

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

7. ENTER CORRECTIONS TO ITEM 6 b. PHONE

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 21-DEC-2010

PART II - PRODUCT INFORMATION

10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps

Types of HCT / Ps	Establishment Functions: Recover	Screen	Test	Package	Process	Store	Label	Distribute	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)
a. Bone	X	X				X		X	X			
b. Cartilage	X	X				X		X	X			
c. Cornea	X	X							X			
d. Dura Mater												
e. Embryo ☐ SIP ☐ Directed ☐ Anonymous												
f. Fascia	X	X				X		X	X			
g. Heart Valve	X	X							X			
h. Ligament	X	X				X		X	X			
i. Oocyte ☐ SIP ☐ Directed ☐ Anonymous												
j. Pericardium	X	X				X		X	X			
k. Peripheral Blood Stem Cells ☐ Autologous ☐ Family Related ☐ Allogeneic												
l. Sclera												
m. Semen ☐ SIP ☐ Directed ☐ Anonymous												
n. Skin	X	X				X		X	X			
o. Somatic Cell Therapy Products ☐ Autologous ☐ Family Related ☐ Allogeneic												
p. Tendon	X	X				X		X	X			
q. Umbilical Cord Blood Stem Cells ☐ Autologous ☐ Family Related ☐ Allogeneic												
r. Vascular Graft	X	X							X			
s. Peritoneal Membrane	X	X				X		X	X			
t.												
u.												
v.												

See Instructions for OMB Statement FORM APPROVED: OMB No. 0910-0543. Expiration Date: 1/31/14

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: 3000718784

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

VALIDATION--FOR FDA USE ONLY 1
VALIDATED BY FDA:08-DEC-2011
DISTRICT: Cincinnati
PRINTED BY FDA:15-DEC-2011

PART I - ESTABLISHMENT INFORMATION

3. OTHER FDA REGISTRATIONS
a. BLOOD FDA 2830 NO.
b. DEVICES FDA 2891 NO.
c. DRUG FDA 2656 NO.

4. PHYSICAL LOCATION *(Include legal name, number and street, city, state, country, and post office code)*
Community Blood Center dba Community Tissue Services
2736 N. Holland-Sylvania Road
Toledo, Ohio 43615

a. PHONE 419-536-4924 EXT
b. ☐ SATELLITE RECOVERY ESTABLISHMENT
(MANUFACTURING ESTABLISHMENT FEI NO.________________)
c. ☐ TESTING FOR MICRO-ORGANISMS ONLY

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

7. ENTER CORRECTIONS TO ITEM 6 b. PHONE

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 07-DEC-2011

PART II - PRODUCT INFORMATION

10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps

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				
a. Bone	X	X				X		X	X			
b. Cartilage	X	X				X		X	X			
c. Cornea	X	X							X			
d. Dura Mater												
e. Embryo ☐ SIP ☐ Directed ☐ Anonymous												
f. Fascia	X	X				X		X	X			
g. Heart Valve	X	X							X			
h. Ligament	X	X				X		X	X			
i. Oocyte ☐ SIP ☐ Directed ☐ Anonymous												
j. Pericardium	X	X				X		X	X			
k. Peripheral Blood Stem Cells ☐ Autologous ☐ Family Related ☐ Allogeneic												
l. Sclera												
m. Semen ☐ SIP ☐ Directed ☐ Anonymous												
n. Skin	X	X				X		X	X			
o. Somatic Cell Therapy Products ☐ Autologous ☐ Family Related ☐ Allogeneic												
p. Tendon	X	X				X		X	X			
q. Umbilical Cord Blood Stem Cells ☐ Autologous ☐ Family Related ☐ Allogeneic												
r. Vascular Graft	X	X							X			
s. Peritoneal Membrane	X	X				X		X	X			
t.												
u.												
v.												

FORM FDA 3356 (4/08)

See Instructions for OMB Statement FORM APPROVED: OMB No. 0910-0543. Expiration Date: 1/31/14

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: 3000718784

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

VALIDATION--FOR FDA USE ONLY 1
VALIDATED BY FDA:21-NOV-2012
DISTRICT: Cincinnati
PRINTED BY FDA:06-DEC-2012

PART I - ESTABLISHMENT INFORMATION

3. OTHER FDA REGISTRATIONS
a. BLOOD FDA 2830 NO. ____________
b. DEVICES FDA 2891 NO. ____________
c. DRUG FDA 2656 NO. ____________

4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code)
Community Blood Center dba Community Tissue Services

2736 N. Holland-Sylvania Road
Toledo, Ohio 43615

a. PHONE 419-536-4924 EXT
b. ☐ SATELLITE RECOVERY ESTABLISHMENT
(MANUFACTURING ESTABLISHMENT FEI NO.____________)
c. ☐ TESTING FOR MICRO-ORGANISMS ONLY

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

7. ENTER CORRECTIONS TO ITEM 6
b. PHONE

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 20-NOV-2012

PART II - PRODUCT INFORMATION

10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps

Types of HCT / Ps	Establishment Functions: Recover	Screen	Test	Package	Process	Store	Label	Distribute	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)
a. Bone	X	X			X	X		X	X			
b. Cartilage	X	X			X	X		X	X			
c. Cornea	X	X							X			
d. Dura Mater												
e. Embryo ☐ SIP ☐ Directed ☐ Anonymous												
f. Fascia	X	X			X	X		X	X			
g. Heart Valve	X	X							X			
h. Ligament	X	X			X	X		X	X			
i. Oocyte ☐ SIP ☐ Directed ☐ Anonymous												
j. Pericardium	X	X			X	X		X	X			
k. Peripheral Blood Stem ☐ Autologous ☐ Family Related ☐ Allogeneic												
l. Sclera	X	X							X			
m. Semen ☐ SIP ☐ Directed ☐ Anonymous												
n. Skin	X	X			X	X		X	X			
o. Somatic Cell Therapy Products ☐ Autologous ☐ Family Related ☐ Allogeneic												
p. Tendon	X	X			X	X		X	X			
q. Umbilical Cord Blood ☐ Autologous ☐ Family Related ☐ Allogeneic												
r. Vascular Graft	X	X							X			
s. Peritoneal Membrane	X	X			X	X		X	X			
t.												
u.												
v.												

See Instructions for OMB Statement FORM APPROVED: OMB No. 0910-0543. Expiration Date: 1/31/14

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: 3000718784

2. REASON FOR SUBMISSION

- a. [ ] INITIAL REGISTRATION / LISTING
- b. [X] ANNUAL REGISTRATION / LISTING
- c. [ ] CHANGE IN INFORMATION
- d. [ ] INACTIVE

VALIDATION--FOR FDA USE ONLY 1
VALIDATED BY FDA:19-NOV-2013
DISTRICT: Cincinnati
PRINTED BY FDA:09-DEC-2013

PART I - ESTABLISHMENT INFORMATION

3. OTHER FDA REGISTRATIONS

a. BLOOD FDA 2830 NO. ____

b. DEVICES FDA 2891 NO. ____

c. DRUG FDA 2656 NO. ____

4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code)

Community Blood Center dba Community Tissue Services

2736 N. Holland-Sylvania Road
Toledo, Ohio 43615

a. PHONE 419-536-4924 EXT

b. [ ] SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO.____)

c. [ ] TESTING FOR MICRO-ORGANISMS ONLY

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

7. ENTER CORRECTIONS TO ITEM 6

b. PHONE

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 18-NOV-2013

PART II - PRODUCT INFORMATION

10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps

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				
a. Bone	X	X				X		X	X			
b. Cartilage	X	X				X		X	X			
c. Cornea	X	X							X			
d. Dura Mater												
e. Embryo [ ] SIP [ ] Directed [ ] Anonymous												
f. Fascia	X	X				X		X	X			
g. Heart Valve	X	X							X			
h. Ligament	X	X				X		X	X			
i. Oocyte [ ] SIP [ ] Directed [ ] Anonymous												
j. Pericardium	X	X				X		X	X			
k. Peripheral Blood Stem [ ] Autologous [ ] Family Related [ ] Allogeneic												
l. Sclera	X	X							X			
m. Semen [ ] SIP [ ] Directed [ ] Anonymous												
n. Skin	X	X				X		X	X			
o. Somatic Cell Therapy Products [ ] Autologous [ ] Family Related [ ] Allogeneic												
p. Tendon	X	X				X		X	X			
q. Umbilical Cord Blood [ ] Autologous [ ] Family Related [ ] Allogeneic												
r. Vascular Graft	X	X							X			
s. Peritoneal Membrane	X	X				X		X	X			
t.												
u.												
v.												

See Instructions for OMB Statement   FORM APPROVED: OMB No. 0910-0543. Expiration Date: 1/31/14

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: 3000718784

2. REASON FOR SUBMISSION

a. ☐ INITIAL REGISTRATION / LISTING
b. ☐ ANNUAL REGISTRATION / LISTING
c. ☒ CHANGE IN INFORMATION
d. ☐ INACTIVE

VALIDATION--FOR FDA USE ONLY   1
VALIDATED BY FDA:31-DEC-2013
DISTRICT: Cincinnati
PRINTED BY FDA:27-JAN-2014

PART I - ESTABLISHMENT INFORMATION

3. OTHER FDA REGISTRATIONS

a. BLOOD FDA 2830 NO. ____
b. DEVICES FDA 2891 NO. ____
c. DRUG FDA 2656 NO. ____

4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code)

Community Blood Center dba Community Tissue Services

2736 N. Holland-Sylvania Road
Toledo, Ohio 43615

a. PHONE 419-536-4924   EXT
b. ☐ SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO.________________)
c. ☐ TESTING FOR MICRO-ORGANISMS ONLY

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

7. ENTER CORRECTIONS TO ITEM 6   b. PHONE

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 30-DEC-2013

PART II - PRODUCT INFORMATION

10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps

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				
a. Bone	X	X			X	X		X	X			
b. Cartilage	X	X			X	X		X	X			
c. Cornea	X	X							X			
d. Dura Mater												
e. Embryo ☐ SIP ☐ Directed ☐ Anonymous												
f. Fascia	X	X			X	X		X	X			
g. Heart Valve	X	X							X			
h. Ligament	X	X			X	X		X	X			
i. Oocyte ☐ SIP ☐ Directed ☐ Anonymous												
j. Pericardium	X	X			X	X		X	X			
k. Peripheral Blood Stem ☐ Autologous ☐ Family Related ☐ Allogeneic												
l. Sclera	X	X							X			
m. Semen ☐ SIP ☐ Directed ☐ Anonymous												
n. Skin	X	X			X	X		X	X			
o. Somatic Cell Therapy Products ☐ Autologous ☐ Family Related ☐ Allogeneic												
p. Tendon	X	X			X	X		X	X			
q. Umbilical Cord Blood ☐ Autologous ☐ Family Related ☐ Allogeneic												
r. Vascular Graft	X	X			X				X			
s. Peritoneal Membrane	X	X			X	X		X	X			
t.												
u.												
v.												

See Instructions for OMB Statement. FORM APPROVED:OMB No.0910-0543. Expiration Date: 3/31/2017

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: 3000718784

2. REASON FOR SUBMISSION

a. ☐ INITIAL REGISTRATION / LISTING
b. ☒ ANNUAL REGISTRATION / LISTING
c. ☐ CHANGE IN INFORMATION
d. ☐ INACTIVE

VALIDATION--FOR FDA USE ONLY 1
VALIDATED BY FDA:02-DEC-2014
DISTRICT: Cincinnati
PRINTED BY FDA:22-DEC-2014

PART I - ESTABLISHMENT INFORMATION

3. OTHER FDA REGISTRATIONS

a. BLOOD FDA 2830 NO. ______
b. DEVICES FDA 2891 NO. ______
c. DRUG FDA 2656 NO. ______

4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code)

Community Blood Center dba Community Tissue Services

2736 N. Holland-Sylvania Road
Toledo, Ohio 43615

a. PHONE 419-536-4924 EXT
b. ☐ SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO.________________
c. ☐ TESTING FOR MICRO-ORGANISMS ONLY

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

7. ENTER CORRECTIONS TO ITEM 6

b. PHONE

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 01-DEC-2014

PART II - PRODUCT INFORMATION

10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps

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				
a. Bone	X	X			X	X		X	X			
b. Cartilage	X	X			X	X		X	X			
c. Cornea	X	X							X			
d. Dura Mater												
e. Embryo ☐ SIP ☐ Directed ☐ Anonymous												
f. Fascia	X	X			X	X		X	X			
g. Heart Valve	X	X							X			
h. Ligament	X	X			X	X		X	X			
i. Oocyte ☐ SIP ☐ Directed ☐ Anonymous												
j. Pericardium	X	X			X	X		X	X			
k. Peripheral Blood Stem ☐ Autologous ☐ Family Related ☐ Allogeneic												
l. Sclera	X	X							X			
m. Semen ☐ SIP ☐ Directed ☐ Anonymous												
n. Skin	X	X			X	X		X	X			
o. Somatic Cell Therapy Products ☐ Autologous ☐ Family Related ☐ Allogeneic												
p. Tendon	X	X			X	X		X	X			
q. Umbilical Cord Blood ☐ Autologous ☐ Family Related ☐ Allogeneic												
r. Vascular Graft	X	X			X				X			
s. Peritoneal Membrane	X	X			X	X		X	X			
t.												
u.												
v.												

See Instructions for OMB Statement. FORM APPROVED:OMB No.0910-0543. Expiration Date: 3/31/2017

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: 3000718784

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

VALIDATION--FOR FDA USE ONLY 1
VALIDATED BY FDA:17-NOV-2015
DISTRICT: Cincinnati
PRINTED BY FDA:03-DEC-2015

PART I - ESTABLISHMENT INFORMATION

3. OTHER FDA REGISTRATIONS
a. BLOOD FDA 2830 NO. ______
b. DEVICES FDA 2891 NO. ______
c. DRUG FDA 2656 NO. ______

4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code)
Community Blood Center dba Community Tissue Services

2736 N. Holland-Sylvania Road
Toledo, Ohio 43615

a. PHONE 419-536-4924 EXT
b. ☐ SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO.______)
c. ☐ TESTING FOR MICRO-ORGANISMS ONLY

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

7. ENTER CORRECTIONS TO ITEM 6
b. PHONE

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

PART II - PRODUCT INFORMATION

10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps

Types of HCT / Ps	Recover	Screen	Test	Package	Process	Store	Label	Distribute	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)
a. Bone	X	X			X	X		X	X			
b. Cartilage	X	X			X	X		X	X			
c. Cornea	X	X							X			
d. Dura Mater												
e. Embryo ☐ SIP ☐ Directed ☐ Anonymous												
f. Fascia	X	X			X	X		X	X			
g. Heart Valve	X	X							X			
h. Ligament	X	X			X	X		X	X			
i. Oocyte ☐ SIP ☐ Directed ☐ Anonymous												
j. Pericardium	X	X			X	X		X	X			
k. Peripheral Blood Stem ☐ Autologous ☐ Family Related ☐ Allogeneic												
l. Sclera	X	X							X			
m. Semen ☐ SIP ☐ Directed ☐ Anonymous												
n. Skin	X	X			X	X		X	X			
o. Somatic Cell Therapy Products ☐ Autologous ☐ Family Related ☐ Allogeneic												
p. Tendon	X	X			X	X		X	X			
q. Umbilical Cord Blood ☐ Autologous ☐ Family Related ☐ Allogeneic												
r. Vascular Graft	X	X			X				X			
s. Peritoneal Membrane	X	X			X	X		X	X			
t.												
u.												
v.												