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: 3004623084

**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: 14-DEC-2005
PRINTED BY FDA: 14-DEC-2005
DISTRICT OFFICE: Philadelphia

## 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
7821 Bartram Avenue
Suite B
Philadelphia, Pennsylvania 19153-3233

PHONE 215-937-9662 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 B. Woll, M.D.
b. E-MAIL jwoll@cbccts.org
c. TITLE CEO d. DATE 29-NOV-2005

## PART II - PRODUCT INFORMATION

**10. ESTABLISHMENT FUNCTIONS:**
a [ ] RECOVER c [ ] TEST e [ ] PROCESS g [ ] LABEL
b [ ] SCREEN d [ ] PACKAGE f [X] STORE 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 | | | |
| d. Dura Mater | | | |
| e. Embryo | | | |
| f. Fascia | X | | |
| g. Heart Valve | | | |
| h. Ligament | X | | |
| i. Oocyte | | | |
| j. Pericardium | | | |
| k. Peripheral Blood Stem Cells | | | |
| l. Sclera | | | |
| m. Semen | | | |
| n. Skin | X | | |
| o. Somatic Cells | | | |
| p. Tendon | X | | |
| q. Umbilical Cord Blood Stem Cells | | | |
| r. Vascular Graft | | | |
| s. | | | |
| t. | | | |
| u. | | | |
| v. | | | |

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: 3004623084

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

VALIDATION–FOR FDA USE ONLY

*3004623084*

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

## 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
7821 Bartram Avenue
Suite E
Philadelphia, Pennsylvania 19153-3233

PHONE 215-937-9662 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, M.D.
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, M.D.
b. E-MAIL jwoll@cbccts.org
c. TITLE CEO d. DATE 01-DEC-2006

## PART II - PRODUCT INFORMATION

**10. ESTABLISHMENT FUNCTIONS:**
a [ ] RECOVER c [ ] TEST e [ ] PROCESS g [X] LABEL
b [ ] SCREEN d [ ] PACKAGE f [X] STORE 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 | | | |
| d. Dura Mater | | | |
| e. Embryo | | | |
| f. Fascia | X | | |
| g. Heart Valve | | | |
| h. Ligament | X | | |
| i. Oocyte | | | |
| j. Pericardium | | | |
| k. Peripheral Blood Stem Cells | | | |
| l. Sclera | | | |
| m. Semen | | | |
| n. Skin | X | | |
| o. Somatic Cells | | | |
| p. Tendon | X | | |
| q. Umbilical Cord Blood Stem Cells | | | |
| r. Vascular Graft | | | |
| 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:** 3004623084

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

VALIDATION--FOR FDA USE ONLY 1
*3004623084*
**VALIDATED By FDA:** 12/10/07 **PRINTED By FDA:** 12/27/07
**DISTRICT:** Philadelphia

## 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"
3573 Bristol Pike
Suite 201
Bensalem, Pennsylvania 19020

a. PHONE 215-245-4506 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, M.D.
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, M.D.
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 | | | |
| b. Cartilage | | | | | | X | X | X | X | | | |
| c. Cornea | | | | | | | | | | | | |
| d. Dura Mater | | | | | | | | | | | | |
| e. Embryo ☐ SIP ☐ Directed ☐ Anonymous | | | | | | | | | | | | |
| f. Fascia | | | | | | X | X | X | X | | | |
| g. Heart Valve | | | | | | | | | | | | |
| h. Ligament | | | | | | X | X | X | X | | | |
| i. Oocyte ☐ SIP ☐ Directed ☐ Anonymous | | | | | | | | | | | | |
| j. Pericardium | | | | | | | | | | | | |
| k. Peripheral Blood Stem Cells ☐ Autologous ☐ Family Related ☐ Allogeneic | | | | | | | | | | | | |
| l. Sclera | | | | | | | | | | | | |
| m. Semen ☐ SIP ☐ Directed ☐ Anonymous | | | | | | | | | | | | |
| n. Skin | | | | | | X | X | X | X | | | |
| o. Somatic Cells ☐ Autologous ☐ Family Related ☐ Allogeneic | | | | | | | | | | | | |
| p. Tendon | | | | | | X | X | X | X | | | |
| q. Umbilical Cord Blood Stem Cells ☐ Autologous ☐ Family Related ☐ Allogeneic | | | | | | | | | | | | |
| r. Vascular Graft | | | | | | | | | | | | |
| s. | | | | | | | | | | | | |
| t. | | | | | | | | | | | | |
| 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**
(Field Establishment Identifier)

**FEI:** 3004623084

**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: Philadelphia
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
3573 Bristol Pike
Suite 201
Bensalem, Pennsylvania 19020

a. PHONE 215-245-4506 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, M.D.
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, M.D.

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 | | | |
| b. Cartilage | | | | | | X | X | X | X | | | |
| c. Cornea | | | | | | | | | | | | |
| d. Dura Mater | | | | | | | | | | | | |
| e. Embryo ☐ SIP ☐ Directed ☐ Anonymous | | | | | | | | | | | | |
| f. Fascia | | | | | | X | X | X | X | | | |
| g. Heart Valve | | | | | | | | | | | | |
| h. Ligament | | | | | | X | X | X | X | | | |
| i. Oocyte ☐ SIP ☐ Directed ☐ Anonymous | | | | | | | | | | | | |
| j. Pericardium | | | | | | 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 | | | |
| o. Somatic Cell Therapy Products ☐ Autologous ☐ Family Related ☐ Allogeneic | | | | | | | | | | | | |
| p. Tendon | | | | | | X | X | X | X | | | |
| q. Umbilical Cord Blood Stem Cells ☐ Autologous ☐ Family Related ☐ Allogeneic | | | | | | | | | | | | |
| r. Vascular Graft | | | | | | | | | | | | |
| s. Peritoneal Membrane | | | | | | 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:** 3004623084

**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: Philadelphia
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
3573 Bristol Pike
Suite 201
Bensalem, Pennsylvania 19020

a. PHONE 215-245-4506 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, M.D.
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, M.D.

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

**FORM FDA 3356 (4/08)**

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:** 3004623084

**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: Philadelphia
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
3573 Bristol Pike
Suite 201
Bensalem, Pennsylvania 19020

a. PHONE 215-245-4506 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, M.D.
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, M.D.

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* | | | | | | | | 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 | | | |
| b. Cartilage | | | | | | X | X | X | X | | | |
| c. Cornea | | | | | | | | | | | | |
| d. Dura Mater | | | | | | | | | | | | |
| e. Embryo ☐ SIP ☐ Directed ☐ Anonymous | | | | | | | | | | | | |
| f. Fascia | | | | | | X | X | X | X | | | |
| g. Heart Valve | | | | | | | | | | | | |
| h. Ligament | | | | | | X | X | X | X | | | |
| i. Oocyte ☐ SIP ☐ Directed ☐ Anonymous | | | | | | | | | | | | |
| j. Pericardium | | | | | | 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 | | | |
| o. Somatic Cell Therapy Products ☐ Autologous ☐ Family Related ☐ Allogeneic | | | | | | | | | | | | |
| p. Tendon | | | | | | X | X | X | X | | | |
| q. Umbilical Cord Blood Stem Cells ☐ Autologous ☐ Family Related ☐ Allogeneic | | | | | | | | | | | | |
| r. Vascular Graft | | | | | | | | | | | | |
| s. Peritoneal Membrane | | | | | | X | X | X | X | | | |
| t. | | | | | | | | | | | | |
| 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**
(Field Establishment Identifier)

**FEI:** 3004623084

**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: Philadelphia
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
3573 Bristol Pike
Suite 201
Bensalem, Pennsylvania 19020

a. PHONE 215-245-4506 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, M.D.
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, M.D.

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 | | | |
| b. Cartilage | | | | | | X | X | X | X | | | |
| c. Cornea | | | | | | | | | | | | |
| d. Dura Mater | | | | | | | | | | | | |
| e. Embryo ☐ SIP ☐ Directed ☐ Anonymous | | | | | | | | | | | | |
| f. Fascia | | | | | | X | X | X | X | | | |
| g. Heart Valve | | | | | | | | | | | | |
| h. Ligament | | | | | | X | X | X | X | | | |
| i. Oocyte ☐ SIP ☐ Directed ☐ Anonymous | | | | | | | | | | | | |
| j. Pericardium | | | | | | 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 | | | |
| o. Somatic Cell Therapy Products ☐ Autologous ☐ Family Related ☐ Allogeneic | | | | | | | | | | | | |
| p. Tendon | | | | | | X | X | X | X | | | |
| q. Umbilical Cord Blood Stem Cells ☐ Autologous ☐ Family Related ☐ Allogeneic | | | | | | | | | | | | |
| r. Vascular Graft | | | | | | | | | | | | |
| s. Peritoneal Membrane | | | | | | 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:** 3004623084

**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: Philadelphia
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

3573 Bristol Pike
Suite 201
Bensalem, Pennsylvania 19020

a. PHONE 215-245-4506 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, M.D.
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, M.D.

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

**FORM FDA 3356 (11/11)**

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:** 3004623084

**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-NOV-2013
DISTRICT: Philadelphia
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

3573 Bristol Pike
Suite 201
Bensalem, Pennsylvania 19020

a. PHONE 215-245-4506 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, M.D.
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, M.D.

b. E-MAIL dsmith@cbccts.org

c. TITLE CEO d. DATE 26-NOV-2013

## 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 | | | |
| b. Cartilage | | | | | | X | | X | X | | | |
| c. Cornea | | | | | | | | | | | | |
| d. Dura Mater | | | | | | | | | | | | |
| e. Embryo ☐ SIP ☐ Directed ☐ Anonymous | | | | | | | | | | | | |
| f. Fascia | | | | | | X | | X | X | | | |
| g. Heart Valve | | | | | | | | | | | | |
| h. Ligament | | | | | | X | | X | X | | | |
| i. Oocyte ☐ SIP ☐ Directed ☐ Anonymous | | | | | | | | | | | | |
| j. Pericardium | | | | | | X | | X | X | | | |
| k. Peripheral Blood Stem ☐ Autologous ☐ Family Related ☐ Allogeneic | | | | | | | | | | | | |
| l. Sclera | | | | | | | | | | | | |
| m. Semen ☐ SIP ☐ Directed ☐ Anonymous | | | | | | | | | | | | |
| n. Skin | | | | | | X | | X | X | | | |
| o. Somatic Cell Therapy Products ☐ Autologous ☐ Family Related ☐ Allogeneic | | | | | | | | | | | | |
| p. Tendon | | | | | | X | | X | X | | | |
| q. Umbilical Cord Blood ☐ Autologous ☐ Family Related ☐ Allogeneic | | | | | | | | | | | | |
| r. Vascular Graft | | | | | | | | | | | | |
| s. Peritoneal Membrane | | | | | | 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:** 3004623084

**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: Philadelphia
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

3573 Bristol Pike
Suite 201
Bensalem, Pennsylvania 19020

a. PHONE 215-245-4506 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, M.D.
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, M.D.

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

**FORM FDA - 3356 (5/14)**

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:** 3004623084

**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: Philadelphia
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

3573 Bristol Pike
Suite 201
Bensalem, Pennsylvania 19020

a. PHONE 215-245-4506 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, M.D.
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, M.D.

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