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: 3004104395

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:28-DEC-2010
DISTRICT: San Francisco
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)*

OneLegacy - Bakersfield
1100 Mohawk Street, Suite 150
Bakersfield, California 93309

a. PHONE 661-356-5244 EXT

b. [X] SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. 3005879987

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)*

OneLegacy
Attn: Alan J. Cochran, MHA, CTBS
221 South Figueroa Street, Suite 500
Los Angeles, California 90012

a. PHONE 213-229-5662 EXT

7. ENTER CORRECTIONS TO ITEM 6 b. PHONE

8. U.S. AGENT

a. E-MAIL

9. REPORTING OFFICIAL'S SIGNATURE

a. TYPED NAME Alan J. Cochran, MHA, CTBS

b. E-MAIL acochran@onelegacy.org

c. TITLE VP, Quality Systems d. DATE 15-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			
b. Cartilage	X	X							X			
c. Cornea	X	X							X			
d. Dura Mater												
e. Embryo [ ] SIP [ ] Directed [ ] Anonymous												
f. Fascia	X	X							X			
g. Heart Valve	X	X							X			
h. Ligament	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			
o. Somatic Cell Therapy Products [ ] Autologous [ ] Family Related [ ] Allogeneic												
p. Tendon	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: 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: 3005879987

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:28-DEC-2010
DISTRICT: Los Angeles
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)*

OneLegacy - Los Angeles
1001 Wilshire Blvd., Suite 200
Los Angeles, California 90017

a. PHONE (213) 989-2420 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)*

OneLegacy
Attn: Alan J. Cochran, MHA, CTBS
221 South Figueroa Street, Suite 500
Los Angeles, California 90012

a. PHONE 213-229-5662 EXT

7. ENTER CORRECTIONS TO ITEM 6 b. PHONE

8. U.S. AGENT

a. E-MAIL

9. REPORTING OFFICIAL'S SIGNATURE

a. TYPED NAME Alan J. Cochran, MHA, CTBS
b. E-MAIL acochran@onelegacy.org
c. TITLE VP, Quality Systems d. DATE 15-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			
b. Cartilage	X	X							X			
c. Cornea	X	X							X			
d. Dura Mater												
e. Embryo ☐ SIP ☐ Directed ☐ Anonymous												
f. Fascia	X	X							X			
g. Heart Valve	X	X							X			
h. Ligament	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			
o. Somatic Cell Therapy Products ☐ Autologous ☐ Family Related ☐ Allogeneic												
p. Tendon	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: 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: 3004627938

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:28-DEC-2010
DISTRICT: Los Angeles
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)*

OneLegacy - Redlands
1701 Orange Tree Lane
Redlands, California 92374

a. PHONE 909-801-3701 EXT
b. [X] SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. 3005879987
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)*

OneLegacy
Attn: Alan J. Cochran, MHA, CTBS
221 South Figueroa Street, Suite 500
Los Angeles, California 90012

a. PHONE 213-229-5662 EXT

7. ENTER CORRECTIONS TO ITEM 6 b. PHONE

8. U.S. AGENT

a. E-MAIL

9. REPORTING OFFICIAL'S SIGNATURE

a. TYPED NAME Alan J. Cochran, MHA, CTBS
b. E-MAIL acochran@onelegacy.org
c. TITLE VP, Quality Systems d. DATE 15-DEC-2010

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			
b. Cartilage	X	X							X			
c. Cornea	X	X							X			
d. Dura Mater												
e. Embryo [ ] SIP [ ] Directed [ ] Anonymous												
f. Fascia	X	X							X			
g. Heart Valve	X	X							X			
h. Ligament	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			
o. Somatic Cell Therapy Products [ ] Autologous [ ] Family Related [ ] Allogeneic												
p. Tendon	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: 1/31/14

1

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: 3005880024

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

VALIDATION--FOR FDA USE ONLY
VALIDATED BY FDA:01-AUG-2011
DISTRICT: Los Angeles
PRINTED BY FDA:01-AUG-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)
OneLegacy - Orange, CA
500 City Parkway West, Suite 110
Orange, California 92868

a. PHONE 213-989-2405 EXT
b. [X] SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. 3005879987
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)
OneLegacy
Attn: Alan J. Cochran, MHA, CTBS
221 South Figueroa Street, Suite 500
Los Angeles, California 90012

a. PHONE 213-229-5662 EXT

7. ENTER CORRECTIONS TO ITEM 6 b. PHONE

8. U.S. AGENT

a. E-MAIL

9. REPORTING OFFICIAL'S SIGNATURE

a. TYPED NAME Alan J. Cochran, MHA, CTBS
b. E-MAIL acochran@onelegacy.org
c. TITLE VP, Quality Systems d. DATE 25-JUL-2011

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			
b. Cartilage	X	X							X			
c. Cornea	X	X							X			
d. Dura Mater												
e. Embryo [ ] SIP [ ] Directed [ ] Anonymous												
f. Fascia	X	X							X			
g. Heart Valve	X	X							X			
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	X	X							X			
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	X	X							X			
s.												
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: 3004104395

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:16-DEC-2009
DISTRICT: San Francisco
PRINTED BY FDA:18-DEC-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)*

OneLegacy - Bakersfield
1100 Mohawk Street, Suite 150
Bakersfield, California 93309

a. PHONE 661-635-0279 EXT

b. [X] SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. 3005879987

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)*

OneLegacy
Attn: Alan J. Cochran, MHA, CTBS
221 South Figueroa Street, Suite 500
Los Angeles, California 90012

a. PHONE 213-229-5662 EXT

7. ENTER CORRECTIONS TO ITEM 6

b. PHONE

8. U.S. AGENT

a. E-MAIL

9. REPORTING OFFICIAL'S SIGNATURE

a. TYPED NAME Alan J. Cochran, MHA, CTBS

b. E-MAIL acochran@onelegacy.org

c. TITLE VP, Quality Systems

d. DATE 15-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			
b. Cartilage	X	X							X			
c. Cornea	X	X							X			
d. Dura Mater												
e. Embryo [ ] SIP [ ] Directed [ ] Anonymous												
f. Fascia	X	X							X			
g. Heart Valve	X	X							X			
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	X	X							X			
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 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: 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: 3005879987

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:16-DEC-2009
DISTRICT: Los Angeles
PRINTED BY FDA:18-DEC-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)*

OneLegacy - Los Angeles
1001 Wilshire Blvd., Suite 200
Los Angeles, California 90017

a. PHONE (213) 356-5560 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)*

OneLegacy
Attn: Alan J. Cochran, MHA, CTBS
221 South Figueroa Street, Suite 500
Los Angeles, California 90012

a. PHONE 213-229-5662 EXT

7. ENTER CORRECTIONS TO ITEM 6 b. PHONE

8. U.S. AGENT

a. E-MAIL

9. REPORTING OFFICIAL'S SIGNATURE

a. TYPED NAME Alan J. Cochran, MHA, CTBS
b. E-MAIL acochran@onelegacy.org
c. TITLE VP, Quality Systems d. DATE 15-DEC-2009

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			
b. Cartilage	X	X							X			
c. Cornea	X	X							X			
d. Dura Mater												
e. Embryo ☐ SIP ☐ Directed ☐ Anonymous												
f. Fascia	X	X							X			
g. Heart Valve	X	X							X			
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	X	X							X			
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 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: 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: 3004627938

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:16-DEC-2009
DISTRICT: Los Angeles
PRINTED BY FDA:18-DEC-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)*

OneLegacy - Redlands
1701 Orange Tree Lane
Redlands, California 92374

a. PHONE 909-801-3701 EXT

b. [X] SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. 3005879987

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)*

OneLegacy
Attn: Alan J. Cochran, MHA, CTBS
221 South Figueroa Street, Suite 500
Los Angeles, California 90012

a. PHONE 213-229-5662 EXT

7. ENTER CORRECTIONS TO ITEM 6 b. PHONE

8. U.S. AGENT

a. E-MAIL

9. REPORTING OFFICIAL'S SIGNATURE

a. TYPED NAME Alan J. Cochran, MHA, CTBS

b. E-MAIL acochran@onelegacy.org

c. TITLE VP, Quality Systems d. DATE 15-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			
b. Cartilage	X	X							X			
c. Cornea	X	X							X			
d. Dura Mater												
e. Embryo [ ] SIP [ ] Directed [ ] Anonymous												
f. Fascia	X	X							X			
g. Heart Valve	X	X							X			
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	X	X							X			
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 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: 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: 3005880024

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:16-DEC-2009
DISTRICT: Los Angeles
PRINTED BY FDA:18-DEC-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)*
OneLegacy - Santa Ana
Civic Center Professional Plaza
500 W. Santa Ana Blvd., Ste. 200
Santa Ana, California 92701

a. PHONE 714-245-6360 EXT
b. [X] SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. 3005879987
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)*
OneLegacy
Attn: Alan J. Cochran, MHA, CTBS
221 South Figueroa Street, Suite 500
Los Angeles, California 90012

a. PHONE 213-229-5662 EXT

7. ENTER CORRECTIONS TO ITEM 6   b. PHONE

8. U.S. AGENT

a. E-MAIL

9. REPORTING OFFICIAL'S SIGNATURE

a. TYPED NAME Alan J. Cochran, MHA, CTBS
b. E-MAIL acochran@onelegacy.org
c. TITLE VP, Quality Systems   d. DATE 15-DEC-2009

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			
b. Cartilage	X	X							X			
c. Cornea	X	X							X			
d. Dura Mater												
e. Embryo [ ] SIP [ ] Directed [ ] Anonymous												
f. Fascia	X	X							X			
g. Heart Valve	X	X							X			
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	X	X							X			
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 Stem Cells [ ] Autologous [ ] Family Related [ ] Allogeneic												
r. Vascular Graft	X	X							X			
s.												
t.												
u.												
v.												