

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: 3005033855

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

VALIDATION--FOR FDA USE ONLY  
VALIDATED BY FDA-20-NOV-2011  
DISTRICT: Dallas  
PRINTED BY FDA-23-NOV-2011

14. PROPRIETARY NAME(S)

**PART II - PRODUCT INFORMATION**

**10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps**

**Establishment Functions**

Types of HCT / Ps	Establishment Functions						
	Recover	Screen	Test	Package	Process	Store	Label

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

**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)

Fairfax Cryobank - Austin  
4201 Marathon Boulevard  
Suite 303A  
Austin, Texas 78756-3436

a. PHONE 512-206-0408 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)

Fairfax Cryobank  
Attn: Megan Taylor  
3015 Williams Drive  
Suite 110  
Fairfax, Virginia 22031

a. PHONE 800-338-8407 EXT \_\_\_\_\_  
b. PHONE \_\_\_\_\_

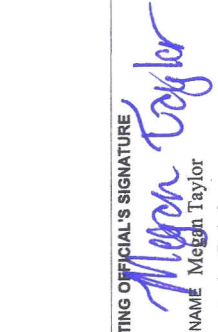
**7. ENTER CORRECTIONS TO ITEM 6**

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**8. U.S. AGENT**

a. E-MAIL \_\_\_\_\_

**9. REPORTING OFFICIAL'S SIGNATURE**

  
a. TYPED NAME Megan Taylor  
b. E-MAIL mtaylor@givf.com  
c. TITLE Document Administrator  
d. DATE 19-NOV-2011