

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: 3004731690

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

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
3015 Williams Drive
Suite 110
Fairfax, Virginia 22031

a. PHONE 800-338-8407 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

8. U.S. AGENT

a. E-MAIL
REPORTING OFFICIAL'S SIGNATURE
Megan Taylor
a. TYPED NAME Megan Taylor
b. E-MAIL mtaylor@givf.com
c. TITLE Document Administrator
d. DATE 05-DEC-2010

PART II - PRODUCT INFORMATION

Types of HCT / Ps	Establishment Functions					14. PROPRIETARY NAME(S)					
	Recover	Screen	Test	Package	Process		Store	Label	Distribute		
a. Bone											
b. Cartilage											
c. Cornea											
d. Dura Mater											
e. Embryo <input checked="" type="checkbox"/> SIP <input checked="" type="checkbox"/> Directed <input type="checkbox"/> Anonymous					X	X	X	X	X	X	
f. Fascia											
g. Heart Valve											
h. Ligament											
i. Oocyte <input checked="" type="checkbox"/> SIP <input checked="" type="checkbox"/> Directed <input checked="" type="checkbox"/> Anonymous					X	X	X	X	X	X	
j. Pericardium											
k. Peripheral Blood Stem Cells <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic											
l. Sclera											
m. Semen <input checked="" type="checkbox"/> SIP <input checked="" type="checkbox"/> Directed <input checked="" type="checkbox"/> Anonymous	X	X		X	X	X	X	X	X	X	
n. Skin											
o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic											
p. Tendon											
q. Umbilical Cord Blood Stem Cells <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic											
r. Vascular Graft											
s. Testicular Tissue					X	X	X	X	X	X	
t. _____											
u. _____											
v. _____											