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: 3001617760

2. REASON FOR SUBMISSION

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

VALIDATION--FOR FDA USE ONLY 1
VALIDATED BY FDA:30-DEC-2010
DISTRICT: Seattle
PRINTED BY FDA:28-FEB-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)

Puget Sound Blood Center & Program,
701 Southwest 39th St
Includes Tissue Servs.@ 501 SW 39th St
Renton, Washington 98057

a. PHONE 206-292-1879 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)

Puget Sound Blood Center
921 Terry Avenue
Attn: Thomas Price, MD
Seattle, Washington 98104

a. PHONE 206-292-4172 EXT

7. ENTER CORRECTIONS TO ITEM 6 b. PHONE

8. U.S. AGENT

a. E-MAIL

9. REPORTING OFFICIAL'S SIGNATURE

a. TYPED NAME Carol S. Anderson, BA, MT(ASCP)

b. E-MAIL Carola@psbc.org

c. TITLE Regulatory Affairs Specialist d. DATE 29-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	X	X	X	X			
b. Cartilage	X	X	X	X	X	X	X	X	X			
c. Cornea			X						X			
d. Dura Mater												
e. Embryo [ ] SIP [ ] Directed [ ] Anonymous												
f. Fascia	X	X	X	X	X	X	X	X	X			
g. Heart Valve	X	X	X	X	X	X	X	X	X			
h. Ligament	X	X	X	X	X	X	X	X	X			
i. Oocyte [ ] SIP [ ] Directed [ ] Anonymous												
j. Pericardium			X	X					X			
k. Peripheral Blood Stem [X] Autologous [X] Family Related [X] Allogeneic			X						X		X	
l. Sclera			X						X			
m. Semen [ ] SIP [X] Directed [ ] Anonymous			X						X			
n. Skin	X	X	X	X	X	X	X	X	X			
o. Somatic Cell Therapy Products [ ] Autologous [ ] Family Related [ ] Allogeneic												
p. Tendon	X	X	X	X	X	X	X	X	X			
q. Umbilical Cord Blood [ ] Autologous [X] Family Related [X] Allogeneic			X						X		X	
r. Vascular Graft	X	X	X	X	X	X	X	X	X			
s. Amniotic Membrane			X	X	X	X	X	X	X			
t. Therapeutic Cells			X						X		X	
u.												
v.												

FORM FDA 3356 (4/08)