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:** 0003071347

**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-2009
DISTRICT: Seattle
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)*

Puget Sound Blood Center & Program, dba Northwest Tissue Services
921 Terry Avenue
Seattle, Washington 98104-1256

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
Attn: Carol S. Anderson, BA, MT(ASCP)
921 Terry Avenue
Seattle, Washington 98104-1256

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