

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. <input type="checkbox"/> INITIAL REGISTRATION / LISTING b. <input type="checkbox"/> ANNUAL REGISTRATION / LISTING c. <input checked="" type="checkbox"/> CHANGE IN INFORMATION d. <input type="checkbox"/> INACTIVE	VALIDATION--FOR FDA USE ONLY VALIDATED BY FDA:23-MAR-2011 DISTRICT: Seattle PRINTED BY FDA:23-MAR-2011
---	--	--	---

PART I - ESTABLISHMENT INFORMATION	PART II - PRODUCT INFORMATION															14. PROPRIETARY NAME(S)		
3. OTHER FDA REGISTRATIONS	10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps										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					
	Establishment Functions																	
	Types of HCT / Ps	Recover	Screen	Test	Package	Process	Store	Label	Distribute									
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 206-292-6500 EXT _____ b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY	a. Bone																	
	b. Cartilage																	
	c. Cornea																	
	d. Dura Mater																	
	e. Embryo <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous																	
	f. Fascia																	
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 _____ b. PHONE _____	g. Heart Valve																	
	h. Ligament																	
	i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous																	
	j. Pericardium																	
	k. Peripheral Blood Stem <input checked="" type="checkbox"/> Autologous <input checked="" type="checkbox"/> Family Related <input checked="" type="checkbox"/> Allogeneic	X	X		X	X	X	X	X	X	X						X	
	l. Sclera																	
m. Semen <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous																		
7. ENTER CORRECTIONS TO ITEM 6 8. U.S. AGENT a. E-MAIL _____	n. Skin																	
	o. Somatic Cell Therapy Products <input checked="" type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic	X			X												X	
	p. Tendon																	
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 17-MAR-2011	q. Umbilical Cord Blood <input type="checkbox"/> Autologous <input checked="" type="checkbox"/> Family Related <input checked="" type="checkbox"/> Allogeneic	X	X		X	X	X	X	X	X							X	
	r. Vascular Graft																	
	s. Amniotic Membrane	X	X					X	X	X	X							
	t. Therapeutic Cells	X	X		X	X	X	X	X	X							X	
	u.																	
v.																		