

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) <i>(See reverse side for instructions)</i>	1. REGISTRATION NUMBER (Field Establishment Identifier) FEI: 1000307349	2. REASON FOR SUBMISSION a. <input type="checkbox"/> INITIAL REGISTRATION / LISTING b. <input checked="" type="checkbox"/> ANNUAL REGISTRATION / LISTING c. <input type="checkbox"/> CHANGE IN INFORMATION d. <input type="checkbox"/> INACTIVE	VALIDATION--FOR FDA USE ONLY VALIDATED BY FDA:24-NOV-2009 DISTRICT: Seattle PRINTED BY FDA:02-DEC-2009
--	--	--	---

PART I - ESTABLISHMENT INFORMATION	PART II - PRODUCT INFORMATION															
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	14. PROPRIETARY NAME(S)	Establishment Functions										
4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code)	Types of HCT / PS					Recover	Screen	Test	Package	Process	Store	Label	Distribute			
a. BLOOD FDA 2830 NO. _____ b. DEVICES FDA 2891 NO. _____ c. DRUG FDA 2656 NO. _____	a. Bone b. Cartilage c. Cornea d. Dura Mater e. Embryo f. Fascia g. Heart Valve h. Ligament i. Oocyte j. Pericardium k. Peripheral Blood Stem l. Sclera m. Semen n. Skin o. Somatic Cell Therapy Products p. Tendon q. Umbilical Cord Blood Stem Cells r. Vascular Graft	<input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous	<input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic	<input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous	<input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous	<input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic	<input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic	<input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic	<input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic	<input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic	<input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic	a. PHONE 907-562-5433 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 f. FASCIA g. HEART VALVE h. LIGAMENT i. OOCYTE j. PERICARDIUM k. PERIPHERAL BLOOD STEM l. SCLERA m. SEMEN n. SKIN o. SOMATIC CELL THERAPY PRODUCTS p. TENDON q. UMBILICAL CORD BLOOD STEM CELLS r. VASCULAR GRAFT	a. PHONE 907-562-5433 EXT _____ b. PHONE _____	a. E-MAIL _____	a. TYPED NAME Bruce Zalneraitis, CTBS, CEBT b. E-MAIL brucez@lifealaska.org c. TITLE Chief Executive Officer d. DATE 23-NOV-2009