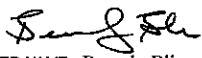


DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/PS) <i>(See reverse side for instructions)</i>	1. REGISTRATION NUMBER (Field Establishment Identifier) FEI: 3006717376	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 1 VALIDATED BY FDA:07-DEC-2009 DISTRICT: Dallas PRINTED BY FDA:18-DEC-2009
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PART I - ESTABLISHMENT INFORMATION	PART II - PRODUCT INFORMATION										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)						
3. OTHER FDA REGISTRATIONS	10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / PS																			
a. BLOOD FDA 2830 NO. _____ b. DEVICES FDA 2891 NO. _____ c. DRUG FDA 2656 NO. _____	Types of HCT / Ps	Establishment Functions								Recover					Screen	Test	Package	Process	Store	Label
4. PHYSICAL LOCATION <i>(Include legal name, number and street, city, state, country, and post office code)</i> RTI Donor Services - El Paso 7618 Boeing Drive, Suite B El Paso, Texas 79925 a. PHONE 915-775-1441 EXT _____ b. <input checked="" type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. 3006042944) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY		a. Bone	X	X										X						
5. ENTER CORRECTIONS TO ITEM 4	b. Cartilage	X	X									X								
	c. Cornea	X	X									X								
6. MAILING ADDRESS OF REPORTING OFFICIAL <i>(Include institution name if applicable, number and street, city, state, country, and post office code)</i> RTI Donor Services Attn: Beverly Bliss 11621 Research Circle Alachua, Florida 32616 a. PHONE 386-418-8888 EXT _____	d. Dura Mater																			
	e. Embryo <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous																			
7. ENTER CORRECTIONS TO ITEM 6 a. _____ b. PHONE _____	f. Fascia	X	X									X								
	g. Heart Valve	X	X									X								
8. U.S. AGENT a. E-MAIL _____	h. Ligament	X	X									X								
	i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous																			
9. REPORTING OFFICIAL'S SIGNATURE  a. TYPED NAME Beverly Bliss b. E-MAIL bbliss@rtix.com c. TITLE Vice President, Donor Services d. DATE 04-DEC-2009	j. Pericardium	X	X									X								
	k. Peripheral Blood Stem <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic																			
	l. Sclera	X	X									X								
	m. Semen <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous																			
	n. Skin	X	X									X								
	o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic																			
	p. Tendon	X	X									X								
	q. Umbilical Cord Blood Stem Cells <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic																			
	r. Vascular Graft	X	X									X								
	s. Nerve Tissue	X	X									X								
	t. _____																			
	u. _____																			
	v. _____																			