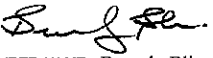


DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION <b>ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES,                  AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/PS)</b> <i>(See reverse side for instructions)</i>	<b>1. REGISTRATION NUMBER</b> (Field Establishment Identifier)  FEI: 3002860769	<b>2. REASON FOR SUBMISSION</b> 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	<b>VALIDATION--FOR FDA USE ONLY</b> 1 VALIDATED BY FDA:07-DEC-2009 DISTRICT: Minneapolis PRINTED BY FDA:18-DEC-2009
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PART I - ESTABLISHMENT INFORMATION	PART II - PRODUCT INFORMATION										11. HCT/PS SERIES 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)
<b>3. OTHER FDA REGISTRATIONS</b> a. BLOOD FDA 2830 NO. _____ b. DEVICES FDA 2891 NO. _____ c. DRUG FDA 2656 NO. _____	<b>10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps</b>													
	<i>Types of HCT / Ps</i>	<i>Establishment Functions</i>												
		Recover	Screen	Test	Package	Process	Store	Label	Distribute					
<b>4. PHYSICAL LOCATION</b> <i>(Include legal name, number and street, city, state, country, and post office code)</i> RTI Donor Services - Midwest Division 8120 Forsythia Street, Suite 2 Middleton, Wisconsin 53562  a. PHONE 608-231-9050 EXT _____ b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY	a. Bone	X	X				X			X				
	b. Cartilage	X	X				X			X				
	c. Cornea													
	d. Dura Mater													
	e. Embryo <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous													
	f. Fascia	X	X				X			X				
<b>5. ENTER CORRECTIONS TO ITEM 4</b>	g. Heart Valve	X	X				X			X				
	h. Ligament	X	X				X			X				
	i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous													
<b>6. MAILING ADDRESS OF REPORTING OFFICIAL</b> <i>(Include institution name if applicable, number and street, city, state, country, and post office code)</i> RTI Donor Services Attn: Beverly Bliss P.O. Box 2650 Alachua, Florida 32616  a. PHONE 386-418-8888 EXT _____ b. PHONE _____	j. Pericardium	X	X				X			X				
	k. Peripheral Blood Stem <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic													
	l. Sclera													
	m. Semen <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous													
<b>7. ENTER CORRECTIONS TO ITEM 6</b>	n. Skin	X	X				X			X				
	o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic													
<b>8. U.S. AGENT</b>  a. E-MAIL _____	p. Tendon	X	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			X				
<b>9. REPORTING OFFICIAL'S SIGNATURE</b>  a. TYPED NAME Beverly Bliss b. E-MAIL bbliss@rtix.com c. TITLE Vice President, RTI Donor Services d. DATE 04-DEC-2009	s. Nerve Tissue	X	X				X			X				
	t.													
	u.													
	v.													