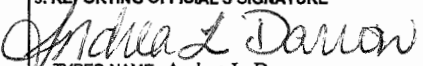


DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION <b>ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES,                  AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/Ps)</b> (See reverse side for instructions)		<b>1. REGISTRATION NUMBER</b> (FDA Establishment Identifier)  FEI: 0002246948	<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:19-NOV-2015 DISTRICT: Florida PRINTED BY FDA:03-DEC-2015												
<b>PART I - ESTABLISHMENT INFORMATION</b>		<b>PART II - PRODUCT INFORMATION</b>							11. HCT/Ps REGULATED IN 21 CFR 1271.10  12. HCT/Ps REGULATED AS MEDICAL DEVICES  13. HCT/Ps REGULATED AS DRUGS OR BIOLOGICAL DRUGS	<b>14. PROPRIETARY                  NAME(S)</b>						
<b>3. OTHER FDA REGISTRATIONS</b> a. BLOOD FDA 2830 NO. FEI: 0002246948 b. DEVICES FDA 2891 NO. _____ c. DRUG FDA 2656 NO. _____		<b>10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps</b>														
<b>4. PHYSICAL LOCATION</b> (Include legal name, number and street, city, state, country, and post office code) Cryo-Cell International, Inc.  700 Brooker Creek Boulevard Suite 1800 Oldsmar, Florida 34677  a. PHONE 813-749-2100 EXT _____ b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY		Types of HCT / Ps	Establishment Functions													
			Recover	Screen	Test	Package	Process	Store	Label	Distribute						
<b>5. ENTER CORRECTIONS TO ITEM 4</b>		a. Bone														
		b. Cartilage														
<b>6. MAILING ADDRESS OF REPORTING OFFICIAL</b> (Include institution name if applicable, number and street, city, state, country, and post office code) Cryo-Cell International, Inc. Attn: Andrea L. Darrow 700 Brooker Creek Boulevard Suite 1800 Oldsmar, Florida 34677  a. PHONE 813-749-2188 EXT _____		c. Cornea														
		d. Dura Mater														
<b>7. ENTER CORRECTIONS TO ITEM 6</b>		e. Embryo <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous														
		f. Fascia														
<b>8. U.S. AGENT</b>  a. E-MAIL _____		g. Heart Valve														
		h. Ligament														
<b>9. REPORTING OFFICIAL'S SIGNATURE</b>  a. TYPED NAME Andrea L. Darrow b. E-MAIL adarrow@cryo-cell.com c. TITLE QA Manager d. DATE 18-NOV-2015		i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous														
		j. Pericardium														
		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														
		n. Skin														
		o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic														
		p. Tendon														
		q. Umbilical Cord Blood <input checked="" type="checkbox"/> Autologous <input checked="" type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic		X			X	X	X	X	X	X				
		r. Vascular Graft														
		s. Menstrual Blood							X	X	X	X				
		t. Umbilical Cord		X			X	X	X	X	X	X				
		u.														
		v.														