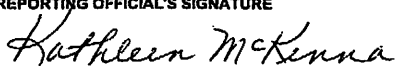


DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION <b>ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES,                  AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/Ps)</b> (See reverse side for instructions)	<b>1. REGISTRATION NUMBER</b> (Field Establishment Identifier)  FEI: 0002275064	<b>2. REASON FOR SUBMISSION</b> 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	<b>VALIDATION--FOR FDA USE ONLY</b> VALIDATED BY FDA:22-SEP-2011 DISTRICT: New Jersey PRINTED BY FDA:27-SEP-2011
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PART I - ESTABLISHMENT INFORMATION	PART II - PRODUCT INFORMATION											14. PROPRIETARY NAME(S)	
<b>3. OTHER FDA REGISTRATIONS</b> a. BLOOD FDA 2830 NO. FEI: 0002275064 b. DEVICES FDA 2891 NO. _____ c. DRUG FDA 2656 NO. _____	<b>10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps</b>										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
	Types of HCT / Ps	Establishment Functions											
		Recover	Screen	Test	Package	Process	Store	Label	Distribute				
<b>4. PHYSICAL LOCATION</b> (Include legal name, number and street, city, state, country, and post office code) Bergen Community Regional Blood Center dba Community Blood Services 970 Linwood Avenue West Paramus, New Jersey 07652  a. PHONE 201-444-3900 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												
	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	
	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 checked="" type="checkbox"/> Allogeneic			X						X		X	
	r. Vascular Graft												
	s.												
	t.												
	u.												
	v.												
<b>5. ENTER CORRECTIONS TO ITEM 4</b>  <b>6. MAILING ADDRESS OF REPORTING OFFICIAL</b> (Include institution name if applicable, number and street, city, state, country, and post office code) Bergen Community Regional Blood Center dba Community Blood Services Attn: Kathleen McKenna, CQIA (ASQ) 970 Linwood Avenue West Paramus, New Jersey 07652  a. PHONE 201-251-3721 EXT _____													
<b>7. ENTER CORRECTIONS TO ITEM 6</b>													
<b>8. U.S. AGENT</b>  a. E-MAIL _____													
<b>9. REPORTING OFFICIAL'S SIGNATURE</b>  a. TYPED NAME Kathleen McKenna, CQIA (ASQ) b. E-MAIL KathleenMc@cbsblood.org c. TITLE AVP QA/RA													
	d. DATE 21-SEP-2011												