

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: 3004521286	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:13-JAN-2012 DISTRICT: New Jersey PRINTED BY FDA:17-JAN-2012
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PART I - ESTABLISHMENT INFORMATION	PART II - PRODUCT INFORMATION																		14. PROPRIETARY NAME(S)			
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	15. HCT/PS REGULATED AS								
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	Distribute												
4. PHYSICAL LOCATION <i>(Include legal name, number and street, city, state, country, and post office code)</i> HLA Registry 1 Pearl Court Allendale, New Jersey 07401 a. PHONE 201-444-3900 EXT 1909 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 Cells <input checked="" type="checkbox"/> Autologous <input checked="" type="checkbox"/> Family Related <input checked="" type="checkbox"/> Allogeneic											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 Stem Cells <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic																						
r. Vascular Graft																						
s.																						
t.																						
u.																						
v.																						
5. ENTER CORRECTIONS TO ITEM 4 6. MAILING ADDRESS OF REPORTING OFFICIAL <i>(Include institution name if applicable, number and street, city, state, country, and post office code)</i> Bergen Community Regional Blood Center Attn: Kathleen McKenna, AVP, QA/RA 970 Linwood Avenue West Paramus, New Jersey 07652 a. PHONE 201-251-3721 EXT _____	7. ENTER CORRECTIONS TO ITEM 6										b. PHONE _____											
8. U.S. AGENT																						
a. E-MAIL																						
9. REPORTING OFFICIAL'S SIGNATURE																						
a. TYPED NAME Kathleen McKenna b. E-MAIL KathleenMc@cbsblood.org c. TITLE AVP Quality Systems d. DATE 27-DEC-2011																						