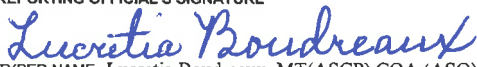


DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/Ps) (See reverse side for instructions)		1. REGISTRATION NUMBER (FDA Establishment Identifier) FEI: 3005233711		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 VALIDATED BY FDA:22-DEC-2016 DISTRICT: New Orleans PRINTED BY FDA:28-DEC-2016							
PART I - ESTABLISHMENT INFORMATION		PART II - PRODUCT INFORMATION							11. HCT/Ps DISCLOSED IN 21 CFR 12.1110	12. HCT/Ps REGULATED AS MEDICAL DEVICES	13. HCT/Ps REGULATED AS DRUGS OR BIOLOGICAL DRUGS	14. PROPRIETARY NAME(S)		
3. OTHER FDA REGISTRATIONS a. BLOOD FDA 2830 NO. FEI: 3006611631 b. DEVICES FDA 2891 NO. _____ c. DRUG FDA 2656 NO. _____		10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps												
		Establishment Functions												
		Types of HCT / Ps	Recover	Screen	Test	Package	Process	Store	Label	Distribute				
4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code) The Blood Center 1310 J.W. Davis Drive Hammond, Louisiana 70403 a. PHONE 985-340-2323 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			
		b. Cartilage			X						X			
		c. Cornea			X						X			
		d. Dura Mater			X						X			
		e. Embryo	<input checked="" type="checkbox"/> SIP <input checked="" type="checkbox"/> Directed <input checked="" type="checkbox"/> Anonymous			X						X		
		f. Fascia				X						X		
		g. Heart Valve				X						X		
		h. Ligament				X						X		
		i. Oocyte	<input checked="" type="checkbox"/> SIP <input checked="" type="checkbox"/> Directed <input checked="" type="checkbox"/> Anonymous			X						X		
		j. Pericardium				X						X		
		k. Peripheral Blood Stem	<input checked="" type="checkbox"/> Autologous <input checked="" type="checkbox"/> Family Related <input checked="" type="checkbox"/> Allogeneic			X						X	X	
		l. Sclera				X						X		
		m. Semen	<input checked="" type="checkbox"/> SIP <input checked="" type="checkbox"/> Directed <input checked="" type="checkbox"/> Anonymous			X						X		
		n. Skin				X						X		
		o. Somatic Cell Therapy Products	<input checked="" type="checkbox"/> Autologous <input checked="" type="checkbox"/> Family Related <input checked="" type="checkbox"/> Allogeneic			X						X	X	
		8. U.S. AGENT		p. Tendon			X					X		
				q. Umbilical Cord Blood			X					X	X	
		r. Vascular Graft			X					X				
a. E-MAIL		s.												
9. REPORTING OFFICIAL'S SIGNATURE  a. TYPED NAME Lucretia Boudreaux, MT(ASCP) CQA (ASQ) b. E-MAIL lboudreaux@thebloodcenter.org c. TITLE Director, QA and Compliance d. DATE 21-DEC-2016		t.												
		u.												
		v.												