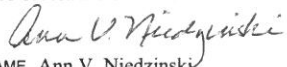


DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/Ps) (See reverse side for instructions)		1. REGISTRATION NUMBER (FDA Establishment Identifier) FEI: 3007203928	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: 12-DEC-2016 DISTRICT: Philadelphia PRINTED BY FDA: 15-DEC-2016											
PART I - ESTABLISHMENT INFORMATION 3. OTHER FDA REGISTRATIONS a. BLOOD FDA 2830 NO. FEI: 3007203928 b. DEVICES FDA 2891 NO. _____ c. DRUG FDA 2656 NO. _____		PART II - PRODUCT INFORMATION 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	14. PROPRIETARY NAME(S)				
		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) LABS - Northeast 401 North 3rd Street Suite 279 Philadelphia, Pennsylvania 19123 a. PHONE 1-800-321-6088 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													
		e. Embryo	<input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous												
		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 a. E-MAIL _____		p. Tendon			X						X		
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					X							X			
9. REPORTING OFFICIAL'S SIGNATURE  a. TYPED NAME Ann V. Niedzinski b. E-MAIL ann_niedzinski@labs-inc.org c. TITLE Sr. Director, Regulatory and Quality d. DATE 11-DEC-2016		s.													
		t.													
		u.													
		v.													