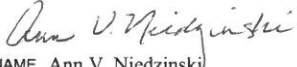


DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION <b>ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES,                  AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/Ps)</b> (See reverse side for instructions)		<b>1. REGISTRATION NUMBER</b> (FDA Establishment Identifier)  FEI: 1000477683	<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	VALIDATION—FOR FDA USE ONLY VALIDATED BY FDA: 12-DEC-2016 DISTRICT: Denver PRINTED BY FDA: 15-DEC-2016								
<b>PART I - ESTABLISHMENT INFORMATION</b>		<b>PART II - PRODUCT INFORMATION</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	14. PROPRIETARY NAME(S)	
<b>3. OTHER FDA REGISTRATIONS</b> a. BLOOD FDA 2830 NO. FEI: 1000477683 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) LABS, Inc.  6933 South Revere Parkway Centennial, Colorado 80112  a. PHONE 303-365-9000 EXT _____ b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY		<b>Types of HCT / Ps</b>		<b>Establishment Functions</b>								
		Recover	Screen	Test	Package	Process	Store	Label	Distribute			
<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) LABS, Inc. Attn: Ann V. Niedzinski 6933 South Revere Parkway Centennial, Colorado 80112  a. PHONE 720-528-4774 EXT _____		a. Bone		X		X				X		
		b. Cartilage		X		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				X		
		g. Heart Valve		X		X				X		
		h. Ligament		X		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				X		
		k. Peripheral Blood Stem	<input checked="" type="checkbox"/> Autologous <input checked="" type="checkbox"/> Family Related <input checked="" type="checkbox"/> Allogeneic	X		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				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	X	
p. Tendon		X		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	X			
r. Vascular Graft		X		X				X				
s. Amniotic Membrane		X		X				X				
t. Nerve Tissue		X		X				X				
u. Placenta		X		X				X	X			
v. Therapeutic Cells		X		X				X	X			
<b>9. REPORTING OFFICIAL'S SIGNATURE</b>  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												

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: 1000477683

**ADDITIONAL INFORMATION:**

Proprietary Name(s):

Additional HCT/Ps:	Functions:	Proprietary Name
Umbilical Cord	Process, Test	11.CFR1271(v) 13.Drug/BioDrug(v)