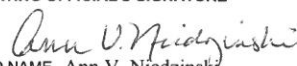


DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/Ps) (See reverse side for instructions)	1. REGISTRATION NUMBER (FDA Establishment Identifier) FEI: 1000477683	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:10-DEC-2017 DISTRICT: Denver PRINTED BY FDA:27-JAN-2018
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PART I - ESTABLISHMENT INFORMATION	PART II - PRODUCT INFORMATION								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)
3. OTHER FDA REGISTRATIONS	10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps											
a. BLOOD FDA 2830 NO. FEI: 1000477683 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 (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	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		
5. ENTER CORRECTIONS TO ITEM 4 6. MAILING ADDRESS OF REPORTING OFFICIAL (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 _____ 7. ENTER CORRECTIONS TO ITEM 6 b. PHONE _____	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	
	8. U.S. AGENT a. E-MAIL _____	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		
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 09-DEC-2017	v. Therapeutic Cells			X		X			X	X		

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

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ADDITIONAL INFORMATION:

Proprietary Name(s):

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