

1. REGISTRATION NUMBER
 (Field Establishment Identifier)
 FEI: 1000477683

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)

2. REASON FOR SUBMISSION
 a. INITIAL REGISTRATION / LISTING
 b. ANNUAL REGISTRATION / LISTING
 c. CHANGE IN INFORMATION
 d. INACTIVE

10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps

Types of HCT / Ps	Establishment Functions						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)
	Recover	Screen	Test	Package	Process	Store				
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 Cells <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. Soman <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 Stem Cells <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			
u. Placenta			X				X			
v. Therapeutic Cells			X				X	X		

PART I - ESTABLISHMENT INFORMATION

3. OTHER FDA REGISTRATIONS
 a. BLOOD FDA 2830 NO. FEI: 1000477683
 b. DEVICES FDA 2891 NO. _____
 c. DRUG FDA 2656 NO. _____

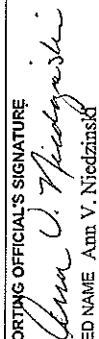
4. PHYSICAL LOCATION (include legal name, number and street, city, state, country, and post office code)
 LABS, Inc.
 6933-B South Revere Parkway
 Centennial, Colorado 80112

5. ENTER CORRECTIONS TO ITEM 4
 a. PHONE 303-365-9000 EXT _____
 b. SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____)
 c. TESTING FOR MICRO-ORGANISMS ONLY

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-B South Revere Parkway
 Centennial, Colorado 80112

7. ENTER CORRECTIONS TO ITEM 6
 a. PHONE 720-528-4774 EXT _____
 b. PHONE _____

8. U.S. AGENT
 a. E-MAIL _____

9. REPORTING OFFICIAL'S SIGNATURE

 a. TYPED NAME Ann V. Niedzinski
 b. E-MAIL ann_niedzinski@labs-inc.org
 c. TITLE Director, Regulatory and Quality
 d. DATE 20-DEC-2011