See Instructions for OMB Statement. FORM APPROVED:OMB No.0910-0543, Expiration Date: 3/31/2017

| 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) | | 1. REGISTRATION NUMBER (FDA Establishment Identifier) | | | | 2. R | REASON FOR SUBMISSION A. INITIAL REGISTRATION / LISTING | | | | | VALIDATION-FOR FDA USE ONLY 1 | | |
|--|----------------------|---|---------|--------|----------|---|---|---------------|-------------|------------|--|---|--|---------|
| | | | | | | a. | | | | | | VALIDATED BY FDA:12-DEC-2016 | | |
| | | FEI: 1000477692 | | | b. | b. X ANNUAL REGISTRATION / LISTI c. CHANGE IN INFORMATION | | | | | NG DISTRICT: Denver PRINTED BY FDA:15-DEC-2016 | | | |
| | | EUES, FEI: 1000477683 | | | | | | | | с. | | | | |
| (See reverse side for instructions) | -, | | | | | d. | INAC | TIVE | | | | | | |
| PART I - ESTABLISHMENT INFORMATION | PART II - PR | ODUCT INFO | RMATI | ON | | | | | | | SE. | MR 12. | 22 R | 3 |
| 3. OTHER FDA REGISTRATIONS | 10. ESTABLISHN | 10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps | | | | | | | SCR R 12 | BEL | D G G G | OLOGICAN NAME(S) | | |
| a. BLOOD FDA 2830 NO. FEI: 1000477683 | Esta | | | | tablishr | ablishment Functions | | | | | PAR | | S S S S S S S S S S S S S S S S S S S | |
| | Types of H | ICT / Ps | _ | | Test | | | Process Store | Label | Distribute | 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 | NAME(S) |
| b. DEVICES FDA 2891 NO | | | Recover | Screen | | Package | Process | | | | | | | |
| c. DRUG FDA 2656 NO. | | | | | | | | | | | | | 0, | |
| 4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and | - | | - | - | | + | - | - | | - | | - | | |
| post office code) | a. Bone | | | | X | | X | | | | X | | | |
| LABS, Inc. | b. Cartilage | | | | X | | X | | | | X | | | |
| | D. Cartilage | | ļ | | | | 1.0 | | | | 1. | | | |
| 6933 South Revere Parkway | c. Cornea | | | | X | | | | | | X | | | |
| Centennial, Colorado 80112 | | | - | | | | | | | | | - | | |
| | d. Dura Mater | | | | | | | | | | | | | |
| | | SIP Directed | | | | | | | | | | | | |
| a. PHONE 303-365-9000 EXT | e. Embryo | Directed Anonymous | | | | | | | | | | | | |
| b. SATELLITE RECOVERY ESTABLISHMENT | | Anonymous | | | | | ** | | | | ** | | | |
| (MANUFACTURING ESTABLISHMENT FEI NO | f. Fascia | | | | X | | X | | | | X | | | |
| c. TESTING FOR MICRO-ORGANISMS ONLY | g. Heart Valve | | | | X | | X | | | | X | | | |
| 5. ENTER CORRECTIONS TO ITEM 4 | g. Flourit Valvo | | | | | | | | | | | | | |
| | h. Ligament | | | | X | | X | | | | X | | | |
| | [2 | SIP | | | | | | | | | - | | | |
| 6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, | | Directed | | | X | | | | | | X | | | |
| number and street, city, state, country, and post office code) LABS, Inc. | | Anonymous | | | | | | | | | | | | |
| Attn: Ann V. Niedzinski | j. Pericardium | | | | X | | X | | | | X | | | |
| 6933 South Revere Parkway | k. Peripheral | Autologous | | | | | | | | | - | | | |
| Centennial, Colorado 80112 | Blood Stem | Family Related Allogeneic | | | X | | X | | | | X | | X | |
| | I. Sclera | gogoor | | | х | | | | | | х | | | |
| | | | | | Α. | | | | | | Α . | | | |
| 7.00.720.520.4274 | | SIP Directed | | | X | | | | | | x | | | |
| a. PHONE 720-528-4774 EXT | | Anonymous | | | Α | | | | | | Α . | | | |
| b. PHONE | n. Skin | | | | X | | X | | | | X | | | |
| | o. Somatic Cell x | Autologous | | - | | - | - | - | | - | - | - | - | |
| | Therapy | Family Related | | | X | | X | | | | X | | X | |
| | Products X | Allogeneic | | - | | - | | _ | | | | - | | |
| . U.S. AGENT | p. Tendon | | | | X | | X | | | | X | | | |
| | q. Umbilical X | Autologous | | | | | | | | | | | | |
| | Cord Blood | Family Related Allogeneic | 1 | | X | | X | | | | X | | X | |
| | | Allogerieic | | - | | | W | + | | - | W | | | |
| a. E-MAIL | r. Vascular Graft | | | | X | | X | | | | X | | | |
| REPORTING OFFICIAL'S SIGNATURE | s. Amniotic Membrane | | | | X | | X | | | | X | | | |
| an V. Neidgindei | t. Nerve Tissue | | | | - | | | - | - | | | | - | |
| TYPED NAME Ann V. Niedzinski) | t. Nerve Hissue | | | | X | | X | | | | X | | | |
| Control Contro | u. Placenta | | | | X | | X | | | | X | | X | |
| E-MAIL ann_niedzinski@labs-inc.org | Theres | | | | | - | | | - | | | - | | |
| TITLE Sr Director Regulatory and Quality d DATE 11-DEC-2016 | v. Therapeutic Cells | | | | V | | v | - 1 | - 1 | | v | | v | |

| | | | See Instructions for OMB Statement. | FORM APPROVED: OMB No. | .0910-0543. Expiration Date: 3/31/2017 |
|---|--------------|----------------------|-------------------------------------|------------------------|--|
| DEPARTMENT OF HEALTH AND HUMAN SERVICES | 1. REGISTI | RATION NUMBER | | | 2 |
| PUBLIC HEALTH SERVICE | (FDA Estat | dishment Identifier) | | | |
| FOOD AND DRUG ADMINISTRATION | | | | | |
| ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, | FEI:](| 000477683 | | | |
| AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/Ps) (See reverse side for instructions) | | | | | |
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| ADDITIONAL INFORMATION: | | | | | |
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| Proprietary Name(s): | | | | | |
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| ΛddithA | onal HCT/Ps: | Functions: | | | Proprietary Name |
| Umbilica | | Process, Test | 11 | CFR1271(v) | 1 Toprictary Italia |
| Ombilica | ai Cord | Process, rest | 13. | Drug/BioDrug(v) | |
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