

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: 3004107906	<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	<b>VALIDATION--FOR FDA USE ONLY</b> VALIDATED BY FDA:25-DEC-2014 DISTRICT: Dallas PRINTED BY FDA:14-NOV-2015
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PART I - ESTABLISHMENT INFORMATION	PART II - PRODUCT INFORMATION																												
<b>3. OTHER FDA REGISTRATIONS</b> a. BLOOD FDA 2830 NO. _____ b. DEVICES FDA 2891 NO. FEI: 3004107906 c. DRUG FDA 2656 NO. _____	<table border="1" style="width:100%; border-collapse: collapse;"> <tr> <th rowspan="2" style="width:40%;">10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps</th> <th colspan="8">Establishment Functions</th> <th rowspan="2" style="writing-mode: vertical-rl; transform: rotate(180deg);">11. HCT/Ps DESCRIBED IN 21 CFR 1271.10</th> <th rowspan="2" style="writing-mode: vertical-rl; transform: rotate(180deg);">12. HCT/Ps REGULATED AS MEDICAL DEVICES</th> <th rowspan="2" style="writing-mode: vertical-rl; transform: rotate(180deg);">13. HCT/Ps REGULATED AS DRUGS OR BIOLOGICAL DRUGS</th> <th rowspan="2" style="width:10%;">14. PROPRIETARY NAME(S)</th> </tr> <tr> <th>Recover</th> <th>Screen</th> <th>Test</th> <th>Package</th> <th>Process</th> <th>Store</th> <th>Label</th> <th>Distribute</th> </tr> <tr> <td style="vertical-align: top;"> <b>4. PHYSICAL LOCATION</b> (Include legal name, number and street, city, state, country, and post office code)                      INCELL Corporation, LLC                       12734 Cimarron Path                      San Antonio, Texas 78249                       a. PHONE 210-877-0100 EXT _____                      b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____)                      c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY                 </td> <td style="vertical-align: top;">                     a. Bone                      b. Cartilage                      c. Cornea                      d. Dura Mater                      e. Embryo  <input type="checkbox"/> SIP  <input type="checkbox"/> Directed  <input type="checkbox"/> Anonymous                      f. Fascia                      g. Heart Valve                      h. Ligament                      i. Oocyte  <input type="checkbox"/> SIP  <input type="checkbox"/> Directed  <input type="checkbox"/> Anonymous                      j. Pericardium                      k. Peripheral Blood Stem  <input checked="" type="checkbox"/> Autologous  <input checked="" type="checkbox"/> Family Related  <input checked="" type="checkbox"/> Allogeneic                      l. Sclera                      m. Semen  <input type="checkbox"/> SIP  <input type="checkbox"/> Directed  <input type="checkbox"/> Anonymous                      n. Skin                      o. Somatic Cell Therapy Products  <input checked="" type="checkbox"/> Autologous  <input checked="" type="checkbox"/> Family Related  <input checked="" type="checkbox"/> Allogeneic                      p. Tendon                      q. Umbilical Cord Blood  <input checked="" type="checkbox"/> Autologous  <input checked="" type="checkbox"/> Family Related  <input checked="" type="checkbox"/> Allogeneic                      r. Vascular Graft                      s. Amniotic Membrane                      t. Parathyroid                      u. Placenta                      v. Adipose Tissue                 </td> <td style="vertical-align: top;"> <b>5. ENTER CORRECTIONS TO ITEM 4</b> </td> <td style="vertical-align: top;"> <b>6. MAILING ADDRESS OF REPORTING OFFICIAL</b> (Include institution name if applicable, number and street, city, state, country, and post office code)                      INCELL Corporation, LLC                      Attn: Mary Pat Moyer, PhD                      12734 Cimarron Path                      San Antonio, Texas 78249                       a. PHONE 210-877-0100 EXT _____                 </td> <td style="vertical-align: top;"> <b>7. ENTER CORRECTIONS TO ITEM 6</b> </td> <td style="vertical-align: top;"> <b>8. U.S. AGENT</b>                       a. E-MAIL _____                 </td> <td style="vertical-align: top;"> <b>9. REPORTING OFFICIAL'S SIGNATURE</b>                       a. 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(See reverse side for instructions)

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**ADDITIONAL INFORMATION:**

**Proprietary Name(s):**

<b>Additional HCT/Ps:</b>	<b>Functions:</b>	<b>Proprietary Name</b>
Placental Blood Derived Cells	Distribute, Label, Package, Process, Store, Test	11.CFR1271(v) 13.Drug/BioDrug(v)
Amniotic Fluid	Distribute, Label, Package, Process, Store, Test	11.CFR1271(v) 12.RegMedDev(v) 13.Drug/BioDrug(v)
Umbilical Cord	Distribute, Label, Package, Process, Store, Test	11.CFR1271(v) 13.Drug/BioDrug(v)
HPC Marrow	Distribute, Label, Package, Process, Store, Test	11.CFR1271(v) 13.Drug/BioDrug(v)
Tumor Cells/Tissue	Distribute, Label, Package, Process, Store, Test	11.CFR1271(v) 12.RegMedDev(v) 13.Drug/BioDrug(v)