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| DEPARTMENT OF HEALTH AND HUMAN SERVICES<br>PUBLIC HEALTH SERVICE<br>FOOD AND DRUG ADMINISTRATION<br><b>ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES,<br/>                 AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/Ps)</b><br>(See reverse side for instructions) | <b>1. REGISTRATION NUMBER</b><br>(FDA Establishment Identifier)<br><br>FEI: 3014254056 | <b>2. REASON FOR SUBMISSION</b><br>a. <input checked="" type="checkbox"/> INITIAL REGISTRATION / LISTING<br>b. <input type="checkbox"/> ANNUAL REGISTRATION / LISTING<br>c. <input type="checkbox"/> CHANGE IN INFORMATION<br>d. <input type="checkbox"/> INACTIVE | VALIDATION--FOR FDA USE ONLY<br>VALIDATED BY FDA:27-FEB-2018<br>DISTRICT: Atlanta<br>PRINTED BY FDA:27-FEB-2018 |
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| PART I - ESTABLISHMENT INFORMATION                                                                                                                                                                                                                                                                                                                                                                                        | PART II - PRODUCT INFORMATION                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | 11. HCT/Ps DESCRIBED IN 21 OFK 12/1/10 | 12. HCT/Ps REGULATED AS MEDICAL DEVICES | 13. HCT/Ps REGULATED AS DRUGS OR BIOLOGICAL DRUGS | 14. PROPRIETARY NAME(S) |                   |                         |            |   |                                        |                                         |                                                   |                         |  |  |                                        |                                         |                                                   |                         |              |        |      |         |         |       |       |            |  |  |  |  |  |  |           |  |  |  |  |  |  |  |  |  |  |  |  |  |               |  |  |  |  |  |  |  |  |  |  |  |  |  |                                                                                                                   |  |  |  |  |  |  |  |  |  |  |  |  |  |           |  |  |  |  |  |  |  |  |  |  |  |  |  |                |  |  |  |  |  |  |  |  |  |  |  |  |  |             |  |  |  |  |  |  |  |  |  |  |  |  |  |                                                                                                                   |  |  |  |  |  |  |  |  |  |  |  |  |  |                |  |  |  |  |  |  |  |  |  |  |  |  |  |                                                                                                                                                |  |  |  |  |  |  |  |  |  |  |  |  |  |           |  |  |  |  |  |  |  |  |  |  |  |  |  |                                                                                                                             |   |   |   |   |   |   |   |   |   |  |  |  |  |         |  |  |  |  |  |  |  |  |  |  |  |  |  |                                                                                                                                                        |  |  |  |  |  |  |  |  |  |  |  |  |  |           |  |  |  |  |  |  |  |  |  |  |  |  |  |                                                                                                                                               |  |  |  |  |  |  |  |  |  |  |  |  |  |                   |  |  |  |  |  |  |  |  |  |  |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |  |
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| <b>3. OTHER FDA REGISTRATIONS</b><br>a. BLOOD FDA 2830 NO. _____<br>b. DEVICES FDA 2891 NO. _____<br>c. DRUG FDA 2656 NO. _____                                                                                                                                                                                                                                                                                           | <b>10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps</b><br><table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th rowspan="2" style="width:30%;">Types of HCT / Ps</th> <th colspan="9" style="text-align: center;">Establishment Functions</th> <th rowspan="2">11. HCT/Ps DESCRIBED IN 21 OFK 12/1/10</th> <th rowspan="2">12. HCT/Ps REGULATED AS MEDICAL DEVICES</th> <th rowspan="2">13. HCT/Ps REGULATED AS DRUGS OR BIOLOGICAL DRUGS</th> <th rowspan="2">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> </thead> </table>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                        |                                         |                                                   |                         | Types of HCT / Ps | Establishment Functions |            |   |                                        |                                         |                                                   |                         |  |  | 11. HCT/Ps DESCRIBED IN 21 OFK 12/1/10 | 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 | Label | Distribute |  |  |  |  |  |  |           |  |  |  |  |  |  |  |  |  |  |  |  |  |               |  |  |  |  |  |  |  |  |  |  |  |  |  |                                                                                                                   |  |  |  |  |  |  |  |  |  |  |  |  |  |           |  |  |  |  |  |  |  |  |  |  |  |  |  |                |  |  |  |  |  |  |  |  |  |  |  |  |  |             |  |  |  |  |  |  |  |  |  |  |  |  |  |                                                                                                                   |  |  |  |  |  |  |  |  |  |  |  |  |  |                |  |  |  |  |  |  |  |  |  |  |  |  |  |                                                                                                                                                |  |  |  |  |  |  |  |  |  |  |  |  |  |           |  |  |  |  |  |  |  |  |  |  |  |  |  |                                                                                                                             |   |   |   |   |   |   |   |   |   |  |  |  |  |         |  |  |  |  |  |  |  |  |  |  |  |  |  |                                                                                                                                                        |  |  |  |  |  |  |  |  |  |  |  |  |  |           |  |  |  |  |  |  |  |  |  |  |  |  |  |                                                                                                                                               |  |  |  |  |  |  |  |  |  |  |  |  |  |                   |  |  |  |  |  |  |  |  |  |  |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Types of HCT / Ps                                                                                                                                                                                                                                                                                                                                                                                                         | Establishment Functions                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                        |                                         |                                                   |                         |                   |                         |            |   | 11. 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|                                                   |                         |  |  |                                        |                                         |                                                   |                         |              |        |      |         |         |       |       |            |  |  |  |  |  |  |           |  |  |  |  |  |  |  |  |  |  |  |  |  |               |  |  |  |  |  |  |  |  |  |  |  |  |  |                                                                                                                   |  |  |  |  |  |  |  |  |  |  |  |  |  |           |  |  |  |  |  |  |  |  |  |  |  |  |  |                |  |  |  |  |  |  |  |  |  |  |  |  |  |             |  |  |  |  |  |  |  |  |  |  |  |  |  |                                                                                                                   |  |  |  |  |  |  |  |  |  |  |  |  |  |                |  |  |  |  |  |  |  |  |  |  |  |  |  |                         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| <b>4. PHYSICAL LOCATION</b> (Include legal name, number and street, city, state, country, and post office code)<br>Xytex Laboratories<br><br>740 Prince Avenue<br>Building 10<br>Athens, Georgia 30606<br><br>a. PHONE 800-277-3210 EXT _____<br>b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____)<br>c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY | <table border="1" style="width:100%; border-collapse: collapse;"> <tr> <td>a. Bone</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr> <td>b. Cartilage</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr> <td>c. Cornea</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr> <td>d. Dura Mater</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr> <td>e. Embryo <input type="checkbox"/> SIP<br/><input type="checkbox"/> Directed<br/><input type="checkbox"/> Anonymous</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr> <td>f. Fascia</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr> <td>g. Heart Valve</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr> <td>h. Ligament</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr> <td>i. Oocyte <input type="checkbox"/> SIP<br/><input type="checkbox"/> Directed<br/><input type="checkbox"/> Anonymous</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr> <td>j. Pericardium</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr> <td>k. Peripheral Blood Stem <input type="checkbox"/> Autologous<br/><input type="checkbox"/> Family Related<br/><input type="checkbox"/> Allogeneic</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr> <td>l. Sclera</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr> <td>m. Semen <input type="checkbox"/> SIP<br/><input type="checkbox"/> Directed<br/><input checked="" type="checkbox"/> Anonymous</td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td style="text-align: center;">X</td><td></td><td></td><td></td><td></td></tr> <tr> <td>n. Skin</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr> <td>o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous<br/><input type="checkbox"/> Family Related<br/><input type="checkbox"/> Allogeneic</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr> <td>p. Tendon</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr> <td>q. Umbilical Cord Blood <input type="checkbox"/> Autologous<br/><input type="checkbox"/> Family Related<br/><input type="checkbox"/> Allogeneic</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr> <td>r. Vascular Graft</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr> <td>s.</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr> <td>t.</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr> <td>u.</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr> <td>v.</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> </table> |                                        |                                         |                                                   |                         | a. Bone           |                         |            |   |                                        |                                         |                                                   |                         |  |  |                                        |                                         |                                                   |                         | b. Cartilage |        |      |         |         |       |       |            |  |  |  |  |  |  | c. Cornea |  |  |  |  |  |  |  |  |  |  |  |  |  | d. Dura Mater |  |  |  |  |  |  |  |  |  |  |  |  |  | e. Embryo <input type="checkbox"/> SIP<br><input type="checkbox"/> Directed<br><input type="checkbox"/> Anonymous |  |  |  |  |  |  |  |  |  |  |  |  |  | f. Fascia |  |  |  |  |  |  |  |  |  |  |  |  |  | g. Heart Valve |  |  |  |  |  |  |  |  |  |  |  |  |  | h. Ligament |  |  |  |  |  |  |  |  |  |  |  |  |  | i. Oocyte <input type="checkbox"/> SIP<br><input type="checkbox"/> Directed<br><input type="checkbox"/> Anonymous |  |  |  |  |  |  |  |  |  |  |  |  |  | j. Pericardium |  |  |  |  |  |  |  |  |  |  |  |  |  | k. Peripheral Blood Stem <input type="checkbox"/> Autologous<br><input type="checkbox"/> Family Related<br><input type="checkbox"/> Allogeneic |  |  |  |  |  |  |  |  |  |  |  |  |  | l. Sclera |  |  |  |  |  |  |  |  |  |  |  |  |  | m. Semen <input type="checkbox"/> SIP<br><input type="checkbox"/> Directed<br><input checked="" type="checkbox"/> Anonymous | X | X | X | X | X | X | X | X | X |  |  |  |  | n. Skin |  |  |  |  |  |  |  |  |  |  |  |  |  | o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous<br><input type="checkbox"/> Family Related<br><input type="checkbox"/> Allogeneic |  |  |  |  |  |  |  |  |  |  |  |  |  | p. Tendon |  |  |  |  |  |  |  |  |  |  |  |  |  | q. Umbilical Cord Blood <input type="checkbox"/> Autologous<br><input type="checkbox"/> Family Related<br><input type="checkbox"/> Allogeneic |  |  |  |  |  |  |  |  |  |  |  |  |  | r. Vascular Graft |  |  |  |  |  |  |  |  |  |  |  |  |  | s. |  |  |  |  |  |  |  |  |  |  |  |  |  | t. |  |  |  |  |  |  |  |  |  |  |  |  |  | u. |  |  |  |  |  |  |  |  |  |  |  |  |  | v. |  |  |  |  |  |  |  |  |  |  |  |  |  |
| a. Bone                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 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| <b>5. ENTER CORRECTIONS TO ITEM 4</b>                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    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| <b>6. MAILING ADDRESS OF REPORTING OFFICIAL</b> (Include institution name if applicable, number and street, city, state, country, and post office code)<br>Xytex Laboratories<br>Attn: James T. Spradlin, MD<br>1100 Emmett Street<br>Augusta, Georgia 30904<br><br>a. PHONE 800-277-3210 EXT _____                                                                                                                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     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| <b>7. ENTER CORRECTIONS TO ITEM 6</b>                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    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| <b>8. U.S. AGENT</b><br><br>a. E-MAIL _____                                                                                                                                                                                                                                                                                                                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             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| <b>9. REPORTING OFFICIAL'S SIGNATURE</b><br><br>a. TYPED NAME James T. Spradlin, MD <br>b. E-MAIL tspradlin@xytex.com<br>c. TITLE Chief Medical & Laboratory Director      d. DATE 03-FEB-2018                                                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               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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: 3014254056

2

**ADDITIONAL INFORMATION:**

This location plans to open and begin operation April 1, 2018.

**Proprietary Name(s):**