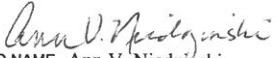


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|---|--|--|---|
| DEPARTMENT OF HEALTH AND HUMAN SERVICES<br>PUBLIC HEALTH SERVICE<br>FOOD AND DRUG ADMINISTRATION<br><b>ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES,<br/>                 AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/Ps)</b><br>(See reverse side for instructions) | <b>1. REGISTRATION NUMBER</b><br>(FDA Establishment Identifier)<br><br>FEI: 3007203928 | <b>2. REASON FOR SUBMISSION</b><br>a. <input type="checkbox"/> INITIAL REGISTRATION / LISTING<br>b. <input checked="" 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:10-DEC-2017<br>DISTRICT: Philadelphia<br>PRINTED BY FDA:27-JAN-2018 |
|---|--|--|---|

| PART I - ESTABLISHMENT INFORMATION  | PART II - PRODUCT INFORMATION   |                   |                         |         |         |       |       |            |                                       |  |                                       |  |  |                         |  |                         |      |         |         |       |       |            |         |  |  |   |  |  |  |  |  |   |  |  |  |              |  |  |   |  |  |  |  |  |   |  |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |               |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |                |  |  |   |  |  |  |  |  |   |  |  |  |             |  |  |   |  |  |  |  |  |   |  |  |  |   |  |  |   |  |  |  |  |  |   |  |  |  |                |  |  |   |  |  |  |  |  |   |  |  |  |  |  |  |   |  |  |  |  |  |   |   |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |  |  |  |   |  |  |  |  |  |   |  |  |  |         |  |  |   |  |  |  |  |  |   |  |  |  |  |  |  |   |  |  |  |  |  |   |   |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |   |  |  |   |  |  |  |  |  |   |   |  |  |                   |  |  |   |  |  |  |  |  |   |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |
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| <b>3. OTHER FDA REGISTRATIONS</b><br>a. BLOOD FDA 2830 NO. FEI: 3007203928<br>b. DEVICES FDA 2891 NO. _____<br>c. DRUG FDA 2656 NO. _____   | <table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th rowspan="2" style="width:45%;">Types of HCT / Ps</th> <th colspan="8" style="text-align: center;">Establishment Functions</th> <th rowspan="2" style="width:5%;">11 HCT/Ps DESCRIBED IN 21 CFR 1271.10</th> <th rowspan="2" style="width:5%;">12 HCT/Ps REGULATED AS MEDICAL DEVICES</th> <th rowspan="2" style="width:5%;">13 HCT/Ps REGULATED AS DRUGS OR BIOLOGICAL DRUGS</th> <th rowspan="2" style="width:15%;">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> <tbody> <tr> <td>a. 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Embryo<br/><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> </tr> <tr> <td>f. Fascia</td> <td></td> <td></td> <td style="text-align: center;">X</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td style="text-align: center;">X</td> <td></td> <td></td> <td></td> </tr> <tr> <td>g. Heart Valve</td> <td></td> <td></td> <td style="text-align: center;">X</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td style="text-align: center;">X</td> <td></td> <td></td> <td></td> </tr> <tr> <td>h. Ligament</td> <td></td> <td></td> <td style="text-align: center;">X</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td style="text-align: center;">X</td> <td></td> <td></td> <td></td> </tr> <tr> <td>i. 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Sclera</td> <td></td> <td></td> <td style="text-align: center;">X</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td style="text-align: center;">X</td> <td></td> <td></td> <td></td> </tr> <tr> <td>m. Semen<br/><input checked="" type="checkbox"/> SIP<br/><input checked="" type="checkbox"/> Directed<br/><input checked="" type="checkbox"/> Anonymous</td> <td></td> <td></td> <td style="text-align: center;">X</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td style="text-align: center;">X</td> <td></td> <td></td> <td></td> </tr> <tr> <td>n. Skin</td> <td></td> <td></td> <td style="text-align: center;">X</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td style="text-align: center;">X</td> <td></td> <td></td> <td></td> </tr> <tr> <td>o. 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Vascular Graft</td> <td></td> <td></td> <td style="text-align: center;">X</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td style="text-align: center;">X</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> </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> </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> </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> </tr> </tbody> </table> | 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 | Label | Distribute | a. Bone |  |  | X |  |  |  |  |  | X |  |  |  | b. Cartilage |  |  | X |  |  |  |  |  | X |  |  |  | c. Cornea |  |  | X |  |  |  |  |  | X |  |  |  | d. Dura Mater |  |  |  |  |  |  |  |  |  |  |  |  | e. Embryo<br><input type="checkbox"/> SIP<br><input type="checkbox"/> Directed<br><input type="checkbox"/> Anonymous |  |  |  |  |  |  |  |  |  |  |  |  | f. Fascia |  |  | X |  |  |  |  |  | X |  |  |  | g. Heart Valve |  |  | X |  |  |  |  |  | X |  |  |  | h. Ligament |  |  | X |  |  |  |  |  | X |  |  |  | i. Oocyte<br><input checked="" type="checkbox"/> SIP<br><input checked="" type="checkbox"/> Directed<br><input checked="" type="checkbox"/> Anonymous |  |  | X |  |  |  |  |  | X |  |  |  | j. Pericardium |  |  | X |  |  |  |  |  | X |  |  |  | k. Peripheral Blood Stem<br><input checked="" type="checkbox"/> Autologous<br><input checked="" type="checkbox"/> Family Related<br><input checked="" type="checkbox"/> Allogeneic |  |  | X |  |  |  |  |  | X | X |  |  | l. Sclera |  |  | X |  |  |  |  |  | X |  |  |  | m. Semen<br><input checked="" type="checkbox"/> SIP<br><input checked="" type="checkbox"/> Directed<br><input checked="" type="checkbox"/> Anonymous |  |  | X |  |  |  |  |  | X |  |  |  | n. Skin |  |  | X |  |  |  |  |  | X |  |  |  | o. Somatic Cell Therapy Products<br><input checked="" type="checkbox"/> Autologous<br><input checked="" type="checkbox"/> Family Related<br><input checked="" type="checkbox"/> Allogeneic |  |  | X |  |  |  |  |  | X | X |  |  | p. Tendon |  |  | X |  |  |  |  |  | X |  |  |  | q. Umbilical Cord Blood<br><input checked="" type="checkbox"/> Autologous<br><input checked="" type="checkbox"/> Family Related<br><input checked="" type="checkbox"/> Allogeneic |  |  | X |  |  |  |  |  | X | X |  |  | r. Vascular Graft |  |  | X |  |  |  |  |  | X |  |  |  | s. |  |  |  |  |  |  |  |  |  |  |  |  | t. |  |  |  |  |  |  |  |  |  |  |  |  | u. |  |  |  |  |  |  |  |  |  |  |  |  | v. |  |  |  |  |  |  |  |  |  |  |  |  |
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|   | Recover   | Screen            | Test                    | Package | Process | Store | Label | Distribute |                                       |  |                                       |  |  |                         |  |                         |      |         |         |       |       |            |         |  |  |   |  |  |  |  |  |   |  |  |  |              |  |  |   |  |  |  |  |  |   |  |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |               |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |                |  |  |   |  |  |  |  |  |   |  |  |  |             |  |  |   |  |  |  |  |  |   |  |  |  |   |  |  |   |  |  |  |  |  |   |  |  |  |                |  |  |   |  |  |  |  |  |   |  |  |  |  |  |  |   |  |  |  |  |  |   |   |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |  |  |  |   |  |  |  |  |  |   |  |  |  |         |  |  |   |  |  |  |  |  |   |  |  |  |  |  |  |   |  |  |  |  |  |   |   |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |   |  |  |   |  |  |  |  |  |   |   |  |  |                   |  |  |   |  |  |  |  |  |   |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |
| a. Bone   |   |                   | X                       |         |         |       |       |            | X                                     |  |                                       |  |  |                         |  |                         |      |         |         |       |       |            |         |  |  |   |  |  |  |  |  |   |  |  |  |              |  |  |   |  |  |  |  |  |   |  |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |               |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |                |  |  |   |  |  |  |  |  |   |  |  |  |             |  |  |   |  |  |  |  |  |   |  |  |  |   |  |  |   |  |  |  |  |  |   |  |  |  |                |  |  |   |  |  |  |  |  |   |  |  |  |  |  |  |   |  |  |  |  |  |   |   |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |  |  |  |   |  |  |  |  |  |   |  |  |  |         |  |  |   |  |  |  |  |  |   |  |  |  |  |  |  |   |  |  |  |  |  |   |   |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |   |  |  |   |  |  |  |  |  |   |   |  |  |                   |  |  |   |  |  |  |  |  |   |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |
| b. Cartilage  |   |                   | X                       |         |         |       |       |            | X                                     |  |                                       |  |  |                         |  |                         |      |         |         |       |       |            |         |  |  |   |  |  |  |  |  |   |  |  |  |              |  |  |   |  |  |  |  |  |   |  |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |               |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |                |  |  |   |  |  |  |  |  |   |  |  |  |             |  |  |   |  |  |  |  |  |   |  |  |  |   |  |  |   |  |  |  |  |  |   |  |  |  |                |  |  |   |  |  |  |  |  |   |  |  |  |  |  |  |   |  |  |  |  |  |   |   |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |  |  |  |   |  |  |  |  |  |   |  |  |  |         |  |  |   |  |  |  |  |  |   |  |  |  |  |  |  |   |  |  |  |  |  |   |   |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |   |  |  |   |  |  |  |  |  |   |   |  |  |                   |  |  |   |  |  |  |  |  |   |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |
| c. Cornea   |   |                   | X                       |         |         |       |       |            | X                                     |  |                                       |  |  |                         |  |                         |      |         |         |       |       |            |         |  |  |   |  |  |  |  |  |   |  |  |  |              |  |  |   |  |  |  |  |  |   |  |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |               |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |                |  |  |   |  |  |  |  |  |   |  |  |  |             |  |  |   |  |  |  |  |  |   |  |  |  |   |  |  |   |  |  |  |  |  |   |  |  |  |                |  |  |   |  |  |  |  |  |   |  |  |  |  |  |  |   |  |  |  |  |  |   |   |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |  |  |  |   |  |  |  |  |  |   |  |  |  |         |  |  |   |  |  |  |  |  |   |  |  |  |  |  |  |   |  |  |  |  |  |   |   |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |   |  |  |   |  |  |  |  |  |   |   |  |  |                   |  |  |   |  |  |  |  |  |   |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |
| d. Dura Mater   |   |                   |                         |         |         |       |       |            |                                       |  |                                       |  |  |                         |  |                         |      |         |         |       |       |            |         |  |  |   |  |  |  |  |  |   |  |  |  |              |  |  |   |  |  |  |  |  |   |  |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |               |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |                |  |  |   |  |  |  |  |  |   |  |  |  |             |  |  |   |  |  |  |  |  |   |  |  |  |   |  |  |   |  |  |  |  |  |   |  |  |  |                |  |  |   |  |  |  |  |  |   |  |  |  |  |  |  |   |  |  |  |  |  |   |   |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |  |  |  |   |  |  |  |  |  |   |  |  |  |         |  |  |   |  |  |  |  |  |   |  |  |  |  |  |  |   |  |  |  |  |  |   |   |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |   |  |  |   |  |  |  |  |  |   |   |  |  |                   |  |  |   |  |  |  |  |  |   |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |
| e. Embryo<br><input type="checkbox"/> SIP<br><input type="checkbox"/> Directed<br><input type="checkbox"/> Anonymous  |   |                   |                         |         |         |       |       |            |                                       |  |                                       |  |  |                         |  |                         |      |         |         |       |       |            |         |  |  |   |  |  |  |  |  |   |  |  |  |              |  |  |   |  |  |  |  |  |   |  |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |               |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |                |  |  |   |  |  |  |  |  |   |  |  |  |             |  |  |   |  |  |  |  |  |   |  |  |  |   |  |  |   |  |  |  |  |  |   |  |  |  |                |  |  |   |  |  |  |  |  |   |  |  |  |  |  |  |   |  |  |  |  |  |   |   |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |  |  |  |   |  |  |  |  |  |   |  |  |  |         |  |  |   |  |  |  |  |  |   |  |  |  |  |  |  |   |  |  |  |  |  |   |   |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |   |  |  |   |  |  |  |  |  |   |   |  |  |                   |  |  |   |  |  |  |  |  |   |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |
| f. Fascia   |   |                   | X                       |         |         |       |       |            | X                                     |  |                                       |  |  |                         |  |                         |      |         |         |       |       |            |         |  |  |   |  |  |  |  |  |   |  |  |  |              |  |  |   |  |  |  |  |  |   |  |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |               |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |                |  |  |   |  |  |  |  |  |   |  |  |  |             |  |  |   |  |  |  |  |  |   |  |  |  |   |  |  |   |  |  |  |  |  |   |  |  |  |                |  |  |   |  |  |  |  |  |   |  |  |  |  |  |  |   |  |  |  |  |  |   |   |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |  |  |  |   |  |  |  |  |  |   |  |  |  |         |  |  |   |  |  |  |  |  |   |  |  |  |  |  |  |   |  |  |  |  |  |   |   |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |   |  |  |   |  |  |  |  |  |   |   |  |  |                   |  |  |   |  |  |  |  |  |   |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |
| g. Heart Valve  |   |                   | X                       |         |         |       |       |            | X                                     |  |                                       |  |  |                         |  |                         |      |         |         |       |       |            |         |  |  |   |  |  |  |  |  |   |  |  |  |              |  |  |   |  |  |  |  |  |   |  |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |               |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |                |  |  |   |  |  |  |  |  |   |  |  |  |             |  |  |   |  |  |  |  |  |   |  |  |  |   |  |  |   |  |  |  |  |  |   |  |  |  |                |  |  |   |  |  |  |  |  |   |  |  |  |  |  |  |   |  |  |  |  |  |   |   |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |  |  |  |   |  |  |  |  |  |   |  |  |  |         |  |  |   |  |  |  |  |  |   |  |  |  |  |  |  |   |  |  |  |  |  |   |   |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |   |  |  |   |  |  |  |  |  |   |   |  |  |                   |  |  |   |  |  |  |  |  |   |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |
| h. Ligament   |   |                   | X                       |         |         |       |       |            | X                                     |  |                                       |  |  |                         |  |                         |      |         |         |       |       |            |         |  |  |   |  |  |  |  |  |   |  |  |  |              |  |  |   |  |  |  |  |  |   |  |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |               |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |                |  |  |   |  |  |  |  |  |   |  |  |  |             |  |  |   |  |  |  |  |  |   |  |  |  |   |  |  |   |  |  |  |  |  |   |  |  |  |                |  |  |   |  |  |  |  |  |   |  |  |  |  |  |  |   |  |  |  |  |  |   |   |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |  |  |  |   |  |  |  |  |  |   |  |  |  |         |  |  |   |  |  |  |  |  |   |  |  |  |  |  |  |   |  |  |  |  |  |   |   |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |   |  |  |   |  |  |  |  |  |   |   |  |  |                   |  |  |   |  |  |  |  |  |   |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |
| i. Oocyte<br><input checked="" type="checkbox"/> SIP<br><input checked="" type="checkbox"/> Directed<br><input checked="" type="checkbox"/> Anonymous   |   |                   | X                       |         |         |       |       |            | X                                     |  |                                       |  |  |                         |  |                         |      |         |         |       |       |            |         |  |  |   |  |  |  |  |  |   |  |  |  |              |  |  |   |  |  |  |  |  |   |  |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |               |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |                |  |  |   |  |  |  |  |  |   |  |  |  |             |  |  |   |  |  |  |  |  |   |  |  |  |   |  |  |   |  |  |  |  |  |   |  |  |  |                |  |  |   |  |  |  |  |  |   |  |  |  |  |  |  |   |  |  |  |  |  |   |   |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |  |  |  |   |  |  |  |  |  |   |  |  |  |         |  |  |   |  |  |  |  |  |   |  |  |  |  |  |  |   |  |  |  |  |  |   |   |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |   |  |  |   |  |  |  |  |  |   |   |  |  |                   |  |  |   |  |  |  |  |  |   |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |
| j. Pericardium  |   |                   | X                       |         |         |       |       |            | X                                     |  |                                       |  |  |                         |  |                         |      |         |         |       |       |            |         |  |  |   |  |  |  |  |  |   |  |  |  |              |  |  |   |  |  |  |  |  |   |  |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |               |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |                |  |  |   |  |  |  |  |  |   |  |  |  |             |  |  |   |  |  |  |  |  |   |  |  |  |   |  |  |   |  |  |  |  |  |   |  |  |  |                |  |  |   |  |  |  |  |  |   |  |  |  |  |  |  |   |  |  |  |  |  |   |   |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |  |  |  |   |  |  |  |  |  |   |  |  |  |         |  |  |   |  |  |  |  |  |   |  |  |  |  |  |  |   |  |  |  |  |  |   |   |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |   |  |  |   |  |  |  |  |  |   |   |  |  |                   |  |  |   |  |  |  |  |  |   |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |
| k. Peripheral Blood Stem<br><input checked="" type="checkbox"/> Autologous<br><input checked="" type="checkbox"/> Family Related<br><input checked="" type="checkbox"/> Allogeneic  |   |                   | X                       |         |         |       |       |            | X                                     | X                                      |                                       |  |  |                         |  |                         |      |         |         |       |       |            |         |  |  |   |  |  |  |  |  |   |  |  |  |              |  |  |   |  |  |  |  |  |   |  |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |               |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |                |  |  |   |  |  |  |  |  |   |  |  |  |             |  |  |   |  |  |  |  |  |   |  |  |  |   |  |  |   |  |  |  |  |  |   |  |  |  |                |  |  |   |  |  |  |  |  |   |  |  |  |  |  |  |   |  |  |  |  |  |   |   |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |  |  |  |   |  |  |  |  |  |   |  |  |  |         |  |  |   |  |  |  |  |  |   |  |  |  |  |  |  |   |  |  |  |  |  |   |   |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |   |  |  |   |  |  |  |  |  |   |   |  |  |                   |  |  |   |  |  |  |  |  |   |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |
| l. Sclera   |   |                   | X                       |         |         |       |       |            | X                                     |  |                                       |  |  |                         |  |                         |      |         |         |       |       |            |         |  |  |   |  |  |  |  |  |   |  |  |  |              |  |  |   |  |  |  |  |  |   |  |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |               |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |                |  |  |   |  |  |  |  |  |   |  |  |  |             |  |  |   |  |  |  |  |  |   |  |  |  |   |  |  |   |  |  |  |  |  |   |  |  |  |                |  |  |   |  |  |  |  |  |   |  |  |  |  |  |  |   |  |  |  |  |  |   |   |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |  |  |  |   |  |  |  |  |  |   |  |  |  |         |  |  |   |  |  |  |  |  |   |  |  |  |  |  |  |   |  |  |  |  |  |   |   |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |   |  |  |   |  |  |  |  |  |   |   |  |  |                   |  |  |   |  |  |  |  |  |   |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |
| m. Semen<br><input checked="" type="checkbox"/> SIP<br><input checked="" type="checkbox"/> Directed<br><input checked="" type="checkbox"/> Anonymous  |   |                   | X                       |         |         |       |       |            | X                                     |  |                                       |  |  |                         |  |                         |      |         |         |       |       |            |         |  |  |   |  |  |  |  |  |   |  |  |  |              |  |  |   |  |  |  |  |  |   |  |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |               |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |                |  |  |   |  |  |  |  |  |   |  |  |  |             |  |  |   |  |  |  |  |  |   |  |  |  |   |  |  |   |  |  |  |  |  |   |  |  |  |                |  |  |   |  |  |  |  |  |   |  |  |  |  |  |  |   |  |  |  |  |  |   |   |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |  |  |  |   |  |  |  |  |  |   |  |  |  |         |  |  |   |  |  |  |  |  |   |  |  |  |  |  |  |   |  |  |  |  |  |   |   |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |   |  |  |   |  |  |  |  |  |   |   |  |  |                   |  |  |   |  |  |  |  |  |   |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |
| n. Skin   |   |                   | X                       |         |         |       |       |            | X                                     |  |                                       |  |  |                         |  |                         |      |         |         |       |       |            |         |  |  |   |  |  |  |  |  |   |  |  |  |              |  |  |   |  |  |  |  |  |   |  |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |               |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |                |  |  |   |  |  |  |  |  |   |  |  |  |             |  |  |   |  |  |  |  |  |   |  |  |  |   |  |  |   |  |  |  |  |  |   |  |  |  |                |  |  |   |  |  |  |  |  |   |  |  |  |  |  |  |   |  |  |  |  |  |   |   |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |  |  |  |   |  |  |  |  |  |   |  |  |  |         |  |  |   |  |  |  |  |  |   |  |  |  |  |  |  |   |  |  |  |  |  |   |   |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |   |  |  |   |  |  |  |  |  |   |   |  |  |                   |  |  |   |  |  |  |  |  |   |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |
| o. Somatic Cell Therapy Products<br><input checked="" type="checkbox"/> Autologous<br><input checked="" type="checkbox"/> Family Related<br><input checked="" type="checkbox"/> Allogeneic  |   |                   | X                       |         |         |       |       |            | X                                     | X                                      |                                       |  |  |                         |  |                         |      |         |         |       |       |            |         |  |  |   |  |  |  |  |  |   |  |  |  |              |  |  |   |  |  |  |  |  |   |  |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |               |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |                |  |  |   |  |  |  |  |  |   |  |  |  |             |  |  |   |  |  |  |  |  |   |  |  |  |   |  |  |   |  |  |  |  |  |   |  |  |  |                |  |  |   |  |  |  |  |  |   |  |  |  |  |  |  |   |  |  |  |  |  |   |   |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |  |  |  |   |  |  |  |  |  |   |  |  |  |         |  |  |   |  |  |  |  |  |   |  |  |  |  |  |  |   |  |  |  |  |  |   |   |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |   |  |  |   |  |  |  |  |  |   |   |  |  |                   |  |  |   |  |  |  |  |  |   |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |
| p. Tendon   |   |                   | X                       |         |         |       |       |            | X                                     |  |                                       |  |  |                         |  |                         |      |         |         |       |       |            |         |  |  |   |  |  |  |  |  |   |  |  |  |              |  |  |   |  |  |  |  |  |   |  |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |               |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |                |  |  |   |  |  |  |  |  |   |  |  |  |             |  |  |   |  |  |  |  |  |   |  |  |  |   |  |  |   |  |  |  |  |  |   |  |  |  |                |  |  |   |  |  |  |  |  |   |  |  |  |  |  |  |   |  |  |  |  |  |   |   |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |  |  |  |   |  |  |  |  |  |   |  |  |  |         |  |  |   |  |  |  |  |  |   |  |  |  |  |  |  |   |  |  |  |  |  |   |   |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |   |  |  |   |  |  |  |  |  |   |   |  |  |                   |  |  |   |  |  |  |  |  |   |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |
| q. Umbilical Cord Blood<br><input checked="" type="checkbox"/> Autologous<br><input checked="" type="checkbox"/> Family Related<br><input checked="" type="checkbox"/> Allogeneic   |   |                   | X                       |         |         |       |       |            | X                                     | X                                      |                                       |  |  |                         |  |                         |      |         |         |       |       |            |         |  |  |   |  |  |  |  |  |   |  |  |  |              |  |  |   |  |  |  |  |  |   |  |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |               |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |                |  |  |   |  |  |  |  |  |   |  |  |  |             |  |  |   |  |  |  |  |  |   |  |  |  |   |  |  |   |  |  |  |  |  |   |  |  |  |                |  |  |   |  |  |  |  |  |   |  |  |  |  |  |  |   |  |  |  |  |  |   |   |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |  |  |  |   |  |  |  |  |  |   |  |  |  |         |  |  |   |  |  |  |  |  |   |  |  |  |  |  |  |   |  |  |  |  |  |   |   |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |   |  |  |   |  |  |  |  |  |   |   |  |  |                   |  |  |   |  |  |  |  |  |   |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |
| r. Vascular Graft   |   |                   | X                       |         |         |       |       |            | X                                     |  |                                       |  |  |                         |  |                         |      |         |         |       |       |            |         |  |  |   |  |  |  |  |  |   |  |  |  |              |  |  |   |  |  |  |  |  |   |  |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |               |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |                |  |  |   |  |  |  |  |  |   |  |  |  |             |  |  |   |  |  |  |  |  |   |  |  |  |   |  |  |   |  |  |  |  |  |   |  |  |  |                |  |  |   |  |  |  |  |  |   |  |  |  |  |  |  |   |  |  |  |  |  |   |   |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |  |  |  |   |  |  |  |  |  |   |  |  |  |         |  |  |   |  |  |  |  |  |   |  |  |  |  |  |  |   |  |  |  |  |  |   |   |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |   |  |  |   |  |  |  |  |  |   |   |  |  |                   |  |  |   |  |  |  |  |  |   |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |
| s.  |   |                   |                         |         |         |       |       |            |                                       |  |                                       |  |  |                         |  |                         |      |         |         |       |       |            |         |  |  |   |  |  |  |  |  |   |  |  |  |              |  |  |   |  |  |  |  |  |   |  |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |               |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |                |  |  |   |  |  |  |  |  |   |  |  |  |             |  |  |   |  |  |  |  |  |   |  |  |  |   |  |  |   |  |  |  |  |  |   |  |  |  |                |  |  |   |  |  |  |  |  |   |  |  |  |  |  |  |   |  |  |  |  |  |   |   |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |  |  |  |   |  |  |  |  |  |   |  |  |  |         |  |  |   |  |  |  |  |  |   |  |  |  |  |  |  |   |  |  |  |  |  |   |   |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |   |  |  |   |  |  |  |  |  |   |   |  |  |                   |  |  |   |  |  |  |  |  |   |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |
| t.  |   |                   |                         |         |         |       |       |            |                                       |  |                                       |  |  |                         |  |                         |      |         |         |       |       |            |         |  |  |   |  |  |  |  |  |   |  |  |  |              |  |  |   |  |  |  |  |  |   |  |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |               |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |                |  |  |   |  |  |  |  |  |   |  |  |  |             |  |  |   |  |  |  |  |  |   |  |  |  |   |  |  |   |  |  |  |  |  |   |  |  |  |                |  |  |   |  |  |  |  |  |   |  |  |  |  |  |  |   |  |  |  |  |  |   |   |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |  |  |  |   |  |  |  |  |  |   |  |  |  |         |  |  |   |  |  |  |  |  |   |  |  |  |  |  |  |   |  |  |  |  |  |   |   |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |   |  |  |   |  |  |  |  |  |   |   |  |  |                   |  |  |   |  |  |  |  |  |   |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |
| u.  |   |                   |                         |         |         |       |       |            |                                       |  |                                       |  |  |                         |  |                         |      |         |         |       |       |            |         |  |  |   |  |  |  |  |  |   |  |  |  |              |  |  |   |  |  |  |  |  |   |  |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |               |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |                |  |  |   |  |  |  |  |  |   |  |  |  |             |  |  |   |  |  |  |  |  |   |  |  |  |   |  |  |   |  |  |  |  |  |   |  |  |  |                |  |  |   |  |  |  |  |  |   |  |  |  |  |  |  |   |  |  |  |  |  |   |   |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |  |  |  |   |  |  |  |  |  |   |  |  |  |         |  |  |   |  |  |  |  |  |   |  |  |  |  |  |  |   |  |  |  |  |  |   |   |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |   |  |  |   |  |  |  |  |  |   |   |  |  |                   |  |  |   |  |  |  |  |  |   |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |
| v.  |   |                   |                         |         |         |       |       |            |                                       |  |                                       |  |  |                         |  |                         |      |         |         |       |       |            |         |  |  |   |  |  |  |  |  |   |  |  |  |              |  |  |   |  |  |  |  |  |   |  |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |               |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |                |  |  |   |  |  |  |  |  |   |  |  |  |             |  |  |   |  |  |  |  |  |   |  |  |  |   |  |  |   |  |  |  |  |  |   |  |  |  |                |  |  |   |  |  |  |  |  |   |  |  |  |  |  |  |   |  |  |  |  |  |   |   |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |  |  |  |   |  |  |  |  |  |   |  |  |  |         |  |  |   |  |  |  |  |  |   |  |  |  |  |  |  |   |  |  |  |  |  |   |   |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |   |  |  |   |  |  |  |  |  |   |   |  |  |                   |  |  |   |  |  |  |  |  |   |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |
| <b>4. PHYSICAL LOCATION</b> (Include legal name, number and street, city, state, country, and post office code)<br>LABS - Northeast<br><br>401 North 3rd Street<br>Suite 279<br>Philadelphia, Pennsylvania 19123<br><br>a. PHONE 1-800-321-6088 EXT _____<br>b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____)<br>c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY |   |                   |                         |         |         |       |       |            |                                       |  |                                       |  |  |                         |  |                         |      |         |         |       |       |            |         |  |  |   |  |  |  |  |  |   |  |  |  |              |  |  |   |  |  |  |  |  |   |  |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |               |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |                |  |  |   |  |  |  |  |  |   |  |  |  |             |  |  |   |  |  |  |  |  |   |  |  |  |   |  |  |   |  |  |  |  |  |   |  |  |  |                |  |  |   |  |  |  |  |  |   |  |  |  |  |  |  |   |  |  |  |  |  |   |   |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |  |  |  |   |  |  |  |  |  |   |  |  |  |         |  |  |   |  |  |  |  |  |   |  |  |  |  |  |  |   |  |  |  |  |  |   |   |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |   |  |  |   |  |  |  |  |  |   |   |  |  |                   |  |  |   |  |  |  |  |  |   |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |
| <b>5. ENTER CORRECTIONS TO ITEM 4</b>   |   |                   |                         |         |         |       |       |            |                                       |  |                                       |  |  |                         |  |                         |      |         |         |       |       |            |         |  |  |   |  |  |  |  |  |   |  |  |  |              |  |  |   |  |  |  |  |  |   |  |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |               |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |                |  |  |   |  |  |  |  |  |   |  |  |  |             |  |  |   |  |  |  |  |  |   |  |  |  |   |  |  |   |  |  |  |  |  |   |  |  |  |                |  |  |   |  |  |  |  |  |   |  |  |  |  |  |  |   |  |  |  |  |  |   |   |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |  |  |  |   |  |  |  |  |  |   |  |  |  |         |  |  |   |  |  |  |  |  |   |  |  |  |  |  |  |   |  |  |  |  |  |   |   |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |   |  |  |   |  |  |  |  |  |   |   |  |  |                   |  |  |   |  |  |  |  |  |   |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |
| <b>6. MAILING ADDRESS OF REPORTING OFFICIAL</b> (Include institution name if applicable, number and street, city, state, country, and post office code)<br>LABS, Inc<br>Attn: Ann V. Niedzinski<br>6933 South Revere Parkway<br>Centennial, Colorado 80112<br><br>a. PHONE 720-528-4774 EXT _____   |   |                   |                         |         |         |       |       |            |                                       |  |                                       |  |  |                         |  |                         |      |         |         |       |       |            |         |  |  |   |  |  |  |  |  |   |  |  |  |              |  |  |   |  |  |  |  |  |   |  |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |               |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |                |  |  |   |  |  |  |  |  |   |  |  |  |             |  |  |   |  |  |  |  |  |   |  |  |  |   |  |  |   |  |  |  |  |  |   |  |  |  |                |  |  |   |  |  |  |  |  |   |  |  |  |  |  |  |   |  |  |  |  |  |   |   |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |  |  |  |   |  |  |  |  |  |   |  |  |  |         |  |  |   |  |  |  |  |  |   |  |  |  |  |  |  |   |  |  |  |  |  |   |   |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |   |  |  |   |  |  |  |  |  |   |   |  |  |                   |  |  |   |  |  |  |  |  |   |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |
| <b>7. ENTER CORRECTIONS TO ITEM 6</b>   |   |                   |                         |         |         |       |       |            |                                       |  |                                       |  |  |                         |  |                         |      |         |         |       |       |            |         |  |  |   |  |  |  |  |  |   |  |  |  |              |  |  |   |  |  |  |  |  |   |  |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |               |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |                |  |  |   |  |  |  |  |  |   |  |  |  |             |  |  |   |  |  |  |  |  |   |  |  |  |   |  |  |   |  |  |  |  |  |   |  |  |  |                |  |  |   |  |  |  |  |  |   |  |  |  |  |  |  |   |  |  |  |  |  |   |   |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |  |  |  |   |  |  |  |  |  |   |  |  |  |         |  |  |   |  |  |  |  |  |   |  |  |  |  |  |  |   |  |  |  |  |  |   |   |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |   |  |  |   |  |  |  |  |  |   |   |  |  |                   |  |  |   |  |  |  |  |  |   |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |
| <b>8. U.S. AGENT</b><br><br>a. E-MAIL _____   |   |                   |                         |         |         |       |       |            |                                       |  |                                       |  |  |                         |  |                         |      |         |         |       |       |            |         |  |  |   |  |  |  |  |  |   |  |  |  |              |  |  |   |  |  |  |  |  |   |  |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |               |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |                |  |  |   |  |  |  |  |  |   |  |  |  |             |  |  |   |  |  |  |  |  |   |  |  |  |   |  |  |   |  |  |  |  |  |   |  |  |  |                |  |  |   |  |  |  |  |  |   |  |  |  |  |  |  |   |  |  |  |  |  |   |   |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |  |  |  |   |  |  |  |  |  |   |  |  |  |         |  |  |   |  |  |  |  |  |   |  |  |  |  |  |  |   |  |  |  |  |  |   |   |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |   |  |  |   |  |  |  |  |  |   |   |  |  |                   |  |  |   |  |  |  |  |  |   |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |
| <b>9. REPORTING OFFICIAL'S SIGNATURE</b><br><br>a. TYPED NAME Ann V. Niedzinski<br>b. E-MAIL ann_niedzinski@labs-inc.org<br>c. TITLE Sr. Director, Regulatory and Quality<br>d. DATE 09-DEC-2017   |   |                   |                         |         |         |       |       |            |                                       |  |                                       |  |  |                         |  |                         |      |         |         |       |       |            |         |  |  |   |  |  |  |  |  |   |  |  |  |              |  |  |   |  |  |  |  |  |   |  |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |               |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |                |  |  |   |  |  |  |  |  |   |  |  |  |             |  |  |   |  |  |  |  |  |   |  |  |  |   |  |  |   |  |  |  |  |  |   |  |  |  |                |  |  |   |  |  |  |  |  |   |  |  |  |  |  |  |   |  |  |  |  |  |   |   |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |  |  |  |   |  |  |  |  |  |   |  |  |  |         |  |  |   |  |  |  |  |  |   |  |  |  |  |  |  |   |  |  |  |  |  |   |   |  |  |           |  |  |   |  |  |  |  |  |   |  |  |  |   |  |  |   |  |  |  |  |  |   |   |  |  |                   |  |  |   |  |  |  |  |  |   |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |    |  |  |  |  |  |  |  |  |  |  |  |  |