**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.*

**FORM APPROVED: OMB No. 0910-0543. Expiration Date: 3/31/2017**

---

### PART I - ESTABLISHMENT INFORMATION

#### 3. OTHER FDA REGISTRATIONS

- a. BLOOD FDA 2830
- b. DEVICES FDA 2891
- c. DRUG FDA 2656

#### 4. PHYSICAL LOCATION

DCI Donor Services dba Sierra Donor Services  
1760 Creekside Oaks Dr  
Suite 220  
Sacramento, California  
95833

- a. PHONE 916-567-1600  
  - EXT
- b. PHONE 916-567-1600  
  - EXT

#### 5. ENTER CORRECTIONS TO ITEM 4

- a. PHONE 916-567-1600  
  - EXT

#### 6. MAILING ADDRESS OF REPORTING OFFICIAL

Sierra Donor Services  
Attn: Kimber Ramos, BA, CTBS, CEBT  
1760 Creekside Oaks  
Suite 220  
Sacramento, California  
95833

- a. PHONE 916-567-1600  
  - EXT

#### 7. ENTER CORRECTIONS TO ITEM 6

- a. PHONE 916-567-1600  
  - EXT

### PART II - PRODUCT INFORMATION

#### 10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps

<table>
<thead>
<tr>
<th>Establishment Functions</th>
<th>Types of HCT / Ps</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recover</td>
<td>Screen</td>
</tr>
<tr>
<td>a. Bone</td>
<td>X X</td>
</tr>
<tr>
<td>b. Cartilage</td>
<td>X X</td>
</tr>
<tr>
<td>c. Cornea</td>
<td>X X X X X X X X</td>
</tr>
<tr>
<td>d. Dura Mater</td>
<td></td>
</tr>
<tr>
<td>e. Embryo</td>
<td></td>
</tr>
<tr>
<td>f. Fascia</td>
<td>X X</td>
</tr>
<tr>
<td>g. Heart Valve</td>
<td>X X</td>
</tr>
<tr>
<td>h. Ligament</td>
<td>X X</td>
</tr>
<tr>
<td>i. Oocyte</td>
<td></td>
</tr>
<tr>
<td>j. Pericardium</td>
<td>X X</td>
</tr>
<tr>
<td>k. Peripheral Blood Stem</td>
<td></td>
</tr>
<tr>
<td>l. Sclera</td>
<td>X X X X X X X X</td>
</tr>
<tr>
<td>m. Semen</td>
<td></td>
</tr>
<tr>
<td>n. Skin</td>
<td>X X</td>
</tr>
<tr>
<td>o. Somatic Cell Therapy Products</td>
<td></td>
</tr>
<tr>
<td>p. Tendon</td>
<td>X X</td>
</tr>
<tr>
<td>q. Umbilical Cord Blood</td>
<td></td>
</tr>
<tr>
<td>r. Vascular Graft</td>
<td>X X</td>
</tr>
</tbody>
</table>

#### 11. HCT/Ps DESCRIBED IN 21 CFR 1271.10
- Choose one:  
  - a. INITIAL REGISTRATION / LISTING
  - b. ANNUAL REGISTRATION / LISTING
  - c. CHANGE IN INFORMATION
  - d. INACTIVE

#### 12. HCT/Ps REGULATED AS MEDICAL DEVICES
- Choose one:  
  - a. BLOOD FDA 2830
  - b. DEVICES FDA 2891
  - c. DRUG FDA 2656

#### 13. HCT/Ps REGULATED AS DRUGS OR BIOLOGICAL DRUGS

#### 14. PROPRIETARY NAME(S)

- Proprietary Name(s)

---

**FORM FDA - 3356 (5/14)**