

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**

(Field Establishment Identifier)

FEI: 3003562205

**2. REASON FOR SUBMISSION**

- a.  INITIAL REGISTRATION / LISTING
- b.  ANNUAL REGISTRATION / LISTING
- c.  CHANGE IN INFORMATION
- d.  INACTIVE

VALIDATION--FOR FDA USE ONLY  
VALIDATED BY FDA:28-DEC-2010  
DISTRICT: New Orleans  
PRINTED BY FDA:05-JAN-2011

| PART I - ESTABLISHMENT INFORMATION  | PART II - PRODUCT INFORMATION                     |   |        |      |         |         |       |       |            | 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) |
|---|---|---|--------|------|---------|---------|-------|-------|------------|--|---|---|-------------------------|
| 3. OTHER FDA REGISTRATIONS  | 10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps |   |        |      |         |         |       |       |            |  |   |   |                         |
| a. BLOOD FDA 2830 NO. _____<br>b. DEVICES FDA 2891 NO. _____<br>c. DRUG FDA 2656 NO. _____  | <i>Establishment Functions</i>                    |   |        |      |         |         |       |       |            |  |   |   |                         |
|   | <i>Types of HCT / Ps</i>                          | Recover   | Screen | Test | Package | Process | Store | Label | Distribute |  |   |   |                         |
| <b>4. PHYSICAL LOCATION</b> <i>(Include legal name, number and street, city, state, country, and post office code)</i><br>Alabama Eye Bank North Alabama Regional Office<br>250 Governors Drive<br>Medical Hills, Suite 1<br>Huntsville, Alabama 35801<br><br>a. PHONE 256-534-3937 EXT _____<br>b. <input checked="" type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. 3001236642)<br>c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY | a. Bone   |   |        |      |         |         |       |       |            |  |   |   |                         |
|   | b. Cartilage                                      |   |        |      |         |         |       |       |            |  |   |   |                         |
|   | c. Cornea   | X   |        |      | X       |         | X     |       |            | X                                      |   |   |                         |
|   | d. Dura Mater                                     |   |        |      |         |         |       |       |            |  |   |   |                         |
|   | e. Embryo   |   |        |      |         |         |       |       |            |  |   |   |                         |
|   |   | <input type="checkbox"/> SIP<br><input type="checkbox"/> Directed<br><input type="checkbox"/> Anonymous               |        |      |         |         |       |       |            |  |   |   |                         |
|   | f. Fascia   |   |        |      |         |         |       |       |            |  |   |   |                         |
| <b>5. ENTER CORRECTIONS TO ITEM 4</b>   | 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 Cells                    |   |        |      |         |         |       |       |            |  |   |   |                         |
|   |   | <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 type="checkbox"/> Anonymous               |        |      |         |         |       |       |            |  |   |   |                         |
| <b>7. ENTER CORRECTIONS TO ITEM 6</b>   | n. Skin   |   |        |      |         |         |       |       |            |  |   |   |                         |
|   | o. Somatic Cell Therapy Products                  |   |        |      |         |         |       |       |            |  |   |   |                         |
|   |   | <input type="checkbox"/> Autologous<br><input type="checkbox"/> Family Related<br><input type="checkbox"/> Allogeneic |        |      |         |         |       |       |            |  |   |   |                         |
| <b>8. U.S. AGENT</b>  | p. Tendon   |   |        |      |         |         |       |       |            |  |   |   |                         |
|   | q. Umbilical Cord Blood Stem Cells                |   |        |      |         |         |       |       |            |  |   |   |                         |
|   |   | <input type="checkbox"/> Autologous<br><input type="checkbox"/> Family Related<br><input type="checkbox"/> Allogeneic |        |      |         |         |       |       |            |  |   |   |                         |
| a. E-MAIL   | r. Vascular Graft                                 |   |        |      |         |         |       |       |            |  |   |   |                         |
| <b>9. REPORTING OFFICIAL'S SIGNATURE</b>  | s.  |   |        |      |         |         |       |       |            |  |   |   |                         |
|   | t.  |   |        |      |         |         |       |       |            |  |   |   |                         |
| a. TYPED NAME John Fisher, CEBT/CTBS<br>b. E-MAIL jfisher@alabamaeyebank.org<br>c. TITLE Vice President of Operations and Regulat d. DATE 10-DEC-2010   | u.  |   |        |      |         |         |       |       |            |  |   |   |                         |
|   | v.  |   |        |      |         |         |       |       |            |  |   |   |                         |