See Instructions for OMB Statement FORM APPROVED: OMB No. 0910-0543. Expiration Date: 1/31/14

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:** 3000718791

**2. REASON FOR SUBMISSION**

a. [ ] INITIAL REGISTRATION / LISTING
b. [X] ANNUAL REGISTRATION / LISTING
c. [ ] CHANGE IN INFORMATION
d. [ ] INACTIVE

VALIDATION--FOR FDA USE ONLY 1
VALIDATED BY FDA:16-NOV-2011
DISTRICT: Cincinnati
PRINTED BY FDA:23-NOV-2011

## PART I - ESTABLISHMENT INFORMATION

**3. OTHER FDA REGISTRATIONS**

a. BLOOD FDA 2830 NO. _____

b. DEVICES FDA 2891 NO. _____

c. DRUG FDA 2656 NO. _____

**4. PHYSICAL LOCATION** *(Include legal name, number and street, city, state, country, and post office code)*

Central Ohio Lions Eye Bank
262 Neil Avenue
Suite 140
Columbus, Ohio 43215

a. PHONE 614-545-2057 EXT

b. [ ] SATELLITE RECOVERY ESTABLISHMENT
(MANUFACTURING ESTABLISHMENT FEI NO._____

c. [ ] TESTING FOR MICRO-ORGANISMS ONLY

**5. ENTER CORRECTIONS TO ITEM 4**

**6. MAILING ADDRESS OF REPORTING OFFICIAL** *(Include institution name if applicable, number and street, city, state, country, and post office code)*

Central Ohio Lions Eye Bank
Attn: David S. Armstrong
262 Neil Avenue
Suite 140
Columbus, Ohio 43215

a. PHONE 614-545-2057 EXT 2092

**7. ENTER CORRECTIONS TO ITEM 6** b. PHONE

**8. U.S. AGENT**

a. E-MAIL

**9. REPORTING OFFICIAL'S SIGNATURE**

a. TYPED NAME David S. Armstrong

b. E-MAIL darmstrong@coleb.org

c. TITLE Quality Assurance Director d. DATE 15-NOV-2011

## PART II - PRODUCT INFORMATION

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

| *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 | | | | | | | | | | | | |
| b. Cartilage | | | | | | | | | | | | |
| c. Cornea | X | X | | X | X | X | X | X | X | | | |
| d. Dura Mater | | | | | | | | | | | | |
| e. Embryo [ ] SIP [ ] Directed [ ] Anonymous | | | | | | | | | | | | |
| f. Fascia | | | | | | | | | | | | |
| g. Heart Valve | | | | | | | | | | | | |
| h. Ligament | | | | | | | | | | | | |
| i. Oocyte [ ] SIP [ ] Directed [ ] Anonymous | | | | | | | | | | | | |
| j. Pericardium | | | | | | | | | | | | |
| k. Peripheral Blood Stem Cells [ ] Autologous [ ] Family Related [ ] Allogeneic | | | | | | | | | | | | |
| l. Sclera | X | X | | X | X | X | X | X | X | | | |
| m. Semen [ ] SIP [ ] Directed [ ] Anonymous | | | | | | | | | | | | |
| n. Skin | | | | | | | | | | | | |
| o. Somatic Cell Therapy Products [ ] Autologous [ ] Family Related [ ] Allogeneic | | | | | | | | | | | | |
| p. Tendon | | | | | | | | | | | | |
| q. Umbilical Cord Blood Stem Cells [ ] Autologous [ ] Family Related [ ] Allogeneic | | | | | | | | | | | | |
| r. Vascular Graft | | | | | | | | | | | | |
| s. | | | | | | | | | | | | |
| t. | | | | | | | | | | | | |
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| v. | | | | | | | | | | | | |