See Instructions for OMB Statement. FORM APPROVED:OMB No.0910-0543. Expiration Date: 3/31/2017

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: 3001238012

**2. REASON FOR SUBMISSION**
a. ☐ INITIAL REGISTRATION / LISTING
b. ☐ ANNUAL REGISTRATION / LISTING
c. ☒ CHANGE IN INFORMATION
d. ☐ INACTIVE

VALIDATION--FOR FDA USE ONLY 1
VALIDATED BY FDA:16-DEC-2016
DISTRICT: Dallas
PRINTED BY FDA:28-DEC-2016

## 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)
Lone Star Lions Eye Bank

102 E. Wheeler
Manor, Texas 78653

a. PHONE 512-457-0638 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)
Lone Star Lions Eye Bank
Attn: Erica Garcia, CEBT
P.O. Box 347
102 East Wheeler Street
Manor, Texas 78653

a. PHONE 512-457-0638 EXT

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

**8. U.S. AGENT**

a. E-MAIL

**9. REPORTING OFFICIAL'S SIGNATURE**

a. TYPED NAME Erica Garcia, CEBT
b. E-MAIL egarcia@lsleb.org
c. TITLE Director of QA/QC d. DATE 15-DEC-2016

## PART II - PRODUCT INFORMATION

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

| Types of HCT / Ps | Establishment Functions: Recover | Screen | Test | Package | Process | Store | Label | Distribute | 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) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 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 ☐ 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 ☐ Autologous ☐ Family Related ☐ Allogeneic | | | | | | | | | | | | |
| r. Vascular Graft | | | | | | | | | | | | |
| s. | | | | | | | | | | | | |
| t. | | | | | | | | | | | | |
| u. | | | | | | | | | | | | |
| v. | | | | | | | | | | | | |

FORM FDA - 3356 (5/14)