

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
VALIDATED BY FDA:11-DEC-2017
DISTRICT: Dallas
PRINTED BY FDA:27-JAN-2018

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

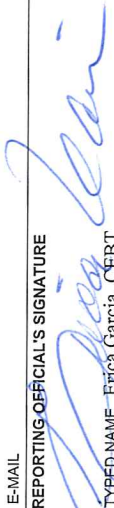
5. ENTER CORRECTIONS TO ITEM 4

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 _____
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 Executive Director
d. DATE 11-DEC-2017

PART II - PRODUCT INFORMATION

Types of HCT / Ps	Establishment Functions					11. HCT/PS REGULATED AS MEDICAL DEVICES	12. HCT/PS REGULATED AS DRUGS OR BIOLOGICAL DRUGS	13. HCT/PS REGULATED AS DRUGS OR BIOLOGICAL DRUGS	14. PROPRIETARY NAME(S)
	Recover	Screen	Test	Package	Process				
a. Bone									
b. Cartilage									
c. Cornea	X	X		X	X	X	X	X	
d. Dura Mater									
e. Embryo <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous									
f. Fascia									
g. Heart Valve									
h. Ligament									
i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous									
j. Pericardium									
k. Peripheral Blood Stem <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic									
l. Sclera <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous	X	X		X	X	X	X	X	
m. Semen									
n. Skin									
o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic									
p. Tendon									
q. Umbilical Cord Blood <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic									
r. Vascular Graft									
s.									
t.									
u.									
v.									