

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)

**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)  
Lions Eye Bank of West Central Ohio  
3309 Office Park Drive  
Dayton, Ohio 45439  
a. PHONE 937-396-1000 EXT \_\_\_\_\_  
b.  SATELLITE RECOVERY ESTABLISHMENT  
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)  
Lions Eye Bank of West Central Ohio  
Attn: Nicole Klein  
3309 Office Park Drive  
Dayton, Ohio 45439  
a. PHONE 937-396-1000 EXT \_\_\_\_\_  
b. PHONE \_\_\_\_\_

7. ENTER CORRECTIONS TO ITEM 6  
8. U.S. AGENT  
a. E-MAIL  
9. REPORTING OFFICIAL'S SIGNATURE  
a. TYPED NAME Nicole Klein  
b. E-MAIL nklein@lebwcoonline.org  
c. TITLE Quality Assurance Director  
d. DATE 16-NOV-2017

1. REGISTRATION NUMBER (FDA Establishment Identifier)  
FEI: 3000718790

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

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)

VALIDATION—FOR FDA USE ONLY  
VALIDATED BY FDA: 16-NOV-2017  
DISTRICT: Cincinnati  
PRINTED BY FDA: 27-JAN-2018

PART II - PRODUCT INFORMATION		10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / PS					Establishment Functions					
Types of HCT / PS	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 <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	X	X		X	X	X	X	X	X			
m. Semen <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous												
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.												