

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: 3000718791

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: 19-NOV-2014
 DISTRICT: Cincinnati
 PRINTED BY FDA: 04-DEC-2014

10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps

Types of HCT / Ps	Establishment Functions						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	X	X	X	X	X	X	X	X
d. Dura Mater																	
e. Embryo																	
f. Fascia																	
g. Heart Valve																	
h. Ligament																	
i. Oocyte																	
j. Pericardium																	
k. Peripheral Blood Stem																	
l. Sclera	X	X		X	X	X	X	X	X	X	X	X	X	X	X	X	X
m. Semen																	
n. Skin																	
o. Somatic Cell Therapy Products																	
p. Tendon																	
q. Umbilical Cord Blood																	
r. Vascular Graft																	
s.																	
t.																	
u.																	
v.																	

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

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 darnstrong@coleb.org

c. TITLE Quality Assurance Director

d. DATE 18-NOV-2014