

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: 16-NOV-2017  
DISTRICT: Cincinnati  
PRINTED BY FDA: 27-JAN-2018

PART I - ESTABLISHMENT INFORMATION		PART II - PRODUCT INFORMATION										
3. OTHER FDA REGISTRATIONS		10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / PS										
		Establishment Functions										
		Types of HCT / PS		Recover	Screen	Test	Package	Process	Store	Label	Distribute	
a. BLOOD FDA 2830 NO.		a. Bone										
b. DEVICES FDA 2891 NO.		b. Cartilage										
c. DRUG FDA 2656 NO.		c. Cornea		X			X	X	X	X	X	X
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		d. Dura Mater										
a. PHONE 614-545-2057 EXT		e. Embryo										
b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT		f. Fascia										
c. <input type="checkbox"/> MANUFACTURING ESTABLISHMENT FEI NO.		g. Heart Valve										
c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY		h. Ligament										
5. ENTER CORRECTIONS TO ITEM 4		i. Oocyte										
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		j. Pericardium										
a. PHONE 614-545-2057 EXT 2092		k. Peripheral Blood Stem										
b. PHONE		l. Sclera		X			X	X	X	X	X	X
7. ENTER CORRECTIONS TO ITEM 6		m. Semen										
a. E-MAIL		n. Skin										
9. REPORTING OFFICIAL'S SIGNATURE		o. Somatic Cell Therapy Products										
a. TYPE NAME David S. Armstrong		p. Tendon										
b. E-MAIL darmstrong@coleb.org		q. Umbilical Cord Blood										
c. TITLE Quality Assurance Director		r. Vascular Graft										
d. DATE 16-NOV-2017		s.										
		t.										
		u.										
		v.										