

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: 3001238368

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:17-NOV-2016
DISTRICT: Kansas City
PRINTED BY FDA:16-DEC-2016

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

PART I - ESTABLISHMENT INFORMATION

3. OTHER FDA REGISTRATIONS
a. BLOOD FDA 2830 NO. _____
b. DEVICES FDA 2891 NO. _____
c. DRUG FDA 2836 NO. _____

4. PHYSICAL LOCATION (Include legal name, number and street, city, state, county, and post office code)
Iowa Lions Eye Bank
2500 Crosspark Rd., W300
Coralville, Iowa 52241

5. ENTER CORRECTIONS TO ITEM 4
a. PHONE 319-335-4888 EXT _____
b. SATELLITE RECOVERY ESTABLISHMENT
(MANUFACTURING ESTABLISHMENT FEI NO. _____)
c. TESTING FOR MICRO-ORGANISMS ONLY

6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, county, and post office code)
Iowa Lions Eye Bank
Attn: Garret D. Locke, MBA, CEBT
2500 Crosspark Rd., W300
Coralville, Iowa 52241

7. ENTER CORRECTIONS TO ITEM 6
a. PHONE 319-335-4888 EXT _____
b. PHONE _____

8. U.S. AGENT

9. REPORTING OFFICIAL'S SIGNATURE
a. TYPED NAME Garret D. Locke, MBA, CEBT
b. E-MAIL garret-locke@uiowa.edu
c. TITLE Director of Compliance & Quality Systems d. DATE 16-NOV-2016

PART II - PRODUCT INFORMATION

10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / PS

Types of HCT / Ps	Establishment Functions						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)
	Recover	Screen	Test	Package	Process	Store				
a. Bone										
b. Cartilage										
c. Cornea	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	
m. Semen										
n. Skin										
o. Somatic Cell Therapy Products										
p. Tendon										
q. Umbilical Cord Blood										
r. Vascular Graft										
s.										
t.										
u.										
v.										