

DEPARTMENT OF HEALTH AND HUMAN SERVICES
 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
(Field Establishment Identifier):
 FEI: 3003347229

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: 27-DEC-2005
 PRINTED BY FDA: 27-DEC-2005
 DISTRICT OFFICE: Kansas City

PART I - ESTABLISHMENT INFORMATION

3. OTHER FDA REGISTRATIONS
 a. BLOOD FDA 2830 NO. _____
 b. DEVICES FDA 2891 NO. _____
 c. DRUG FDA 2856 NO. _____

4. PHYSICAL LOCATION *(Include legal name, number and street, city, state, country, and post office code)*

Heartland Lions Eye Bank
 Northwoods Office Complex
 5742 N. Broadway
 Kansas City, Missouri 64118
 PHONE 816-454-5454 EXT _____

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)*

Missouri Lions Eye Research Foundation
 404 Portland St.
 Columbia, Missouri 65201
 PHONE 573-443-1471 EXT _____

7. ENTER CORRECTIONS TO ITEM 6

8. U.S. AGENT

a. E-MAIL _____ b. PHONE _____

9. REPORTING OFFICIAL'S SIGNATURE

a. TYPED NAME Ronald J. Walkenbach, PhD
 b. E-MAIL rwalkenbach@mlerf.org
 c. TITLE Executive Director d. DATE 12-DEC-2005

PART II - PRODUCT INFORMATION

10. ESTABLISHMENT FUNCTIONS:
 a. RECOVER c. TEST e. PROCESS g. LABEL
 b. SCREEN d. PACKAGE f. STORE h. DISTRIBUTE

TYPES OF HCT/PS	11. HCT/PS DESCRIBED IN 21 CFR 1271.10	12. HCT/PS REGULATED AS MEDICAL DEVICES, DRUGS, OR BIOLOGICAL DRUGS	13. PROPRIETARY NAME(S)	
a. Bone				
b. Cartilage				
c. Cornea		X		
d. Dura Mater				
e. Embryo				
f. Fascia				
g. Heart Valve				
h. Ligament				
i. Oocyte				
j. Pericardium				
k. Peripheral Blood Stem Cells				
l. Sclera		X		
m. Semen				
n. Skin				
o. Somatic Cells				
p. Tendon				
q. Umbilical Cord Blood Stem Cells				
r. Vascular Graft				
s. _____				
t. _____				
u. _____				
v. _____				

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1. REGISTRATION NUMBER
(Find Establishment Identifier):
 FEI: 3002423143

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



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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, county, and post office code)*
 Heartland Lions Eye Bank
 4482 Woodson Rd.
 Suite 7
 St. Louis, Missouri 63134
 PHONE 314-428-4373 EXT _____

5. ENTER CORRECTIONS TO ITEM 4

6. MAILING ADDRESS OF REPORTING OFFICIAL *(Include institution name if applicable, number and street, city, state, county, and post office code)*
 Missouri Lions Eye Research Foundation
 404 Portland St.
 Columbia, Missouri 65201
 PHONE 573-443-1471 EXT _____

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