

VALIDATION--FOR FDA USE ONLY
 VALIDATED BY FDA 02-JUN-2010
 DISTRICT: New Orleans
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2. REASON FOR SUBMISSION
 a. INITIAL REGISTRATION / LISTING
 b. ANNUAL REGISTRATION / LISTING
 c. CHANGE IN INFORMATION
 d. INACTIVE

1. REGISTRATION NUMBER
 (Field Establishment Identifier)
 FEI: 3000215034

10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps

Types of HCT / Ps	Establishment Functions					14. PROPRIETARY NAME(S)
	Recover	Screen	Test	Package	Distribute	
a. Bone						
b. Cartilage						
c. Cornea	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 Cells <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic						
l. Sclera	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 Stem Cells <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic						
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

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)
 Southern Eye Bank
 2701 Kingman Street
 Suite 200
 Metairie, Louisiana 70006

a. PHONE 504-891-3937 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)
 Southern Eye Bank
 Attn: Ken W. Steward, CEBT
 2701 Kingman Street
 Suite 200
 Metairie, Louisiana 70006

a. PHONE 504-891-3937 EXT _____
 b. PHONE _____

7. ENTER CORRECTIONS TO ITEM 6

8. U.S. AGENT

a. E-MAIL

9. REPORTING OFFICIAL'S SIGNATURE

a. TYPED NAME Ken W. Steward, CEBT
 b. E-MAIL ksteward@southerneye.net
 c. TITLE Assist. Executive Director/QA Director
 d. DATE 19-MAY-2010

FORM FDA 3356 (4/08)