See Instructions for OMB Statement

FORM APPROVED: OMB No. 0910-0543. Expiration Date: 8/31/10

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**
(Field Establishment Identifier)

**FEI:** 3000718321

**2. REASON FOR SUBMISSION**

a. ☐ INITIAL REGISTRATION / LISTING
b. ☒ ANNUAL REGISTRATION / LISTING
c. ☐ CHANGE IN INFORMATION
d. ☐ INACTIVE

VALIDATION--FOR FDA USE ONLY 1
VALIDATED BY FDA:15-DEC-2008
DISTRICT: Detroit
PRINTED BY FDA:19-DEC-2008

## 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)*

Michigan Eye-Bank
4889 Venture Dr.
Ann Arbor, Michigan 48108

a. PHONE 734-780-2100 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)*

Midwest Eye-Banks
Attn: Kevin W. Ross
4889 Venture Dr.
Ann Arbor, Michigan 48108

a. PHONE 734-780-2100 EXT

b. PHONE

**7. ENTER CORRECTIONS TO ITEM 6**

**8. U.S. AGENT**

a. E-MAIL

**9. REPORTING OFFICIAL'S SIGNATURE**

a. TYPED NAME Kevin W. Ross

b. E-MAIL kwross@midwesteyebanks.org

c. TITLE President/CEO d. DATE 18-NOV-2008

## 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 | Label | Distribute | | | | |
| a. Bone | | | | | | | | | | | | |
| b. Cartilage | | | | | | | | | | | | |
| c. Cornea | X | X | | X | X | X | X | X | X | | | |
| d. Dura Mater | | | | | | | | | | | | |
| e. Embryo ☐ SIP ☐ Directed ☐ Anonymous | | | | | | | | | | | | |
| f. Fascia | | | | | | | | | | | | |
| g. Heart Valve | | | | | | | | | | | | |
| h. Ligament | | | | | | | | | | | | |
| i. Oocyte ☐ SIP ☐ Directed ☐ Anonymous | | | | | | | | | | | | |
| j. Pericardium | | | | | | | | | | | | |
| k. Peripheral Blood Stem Cells ☐ Autologous ☐ Family Related ☐ Allogeneic | | | | | | | | | | | | |
| l. Sclera | X | X | | X | X | X | X | X | X | | | |
| m. Semen ☐ SIP ☐ Directed ☐ Anonymous | | | | | | | | | | | | |
| n. Skin | | | | | | | | | | | | |
| o. Somatic Cell Therapy Products ☐ Autologous ☐ Family Related ☐ Allogeneic | | | | | | | | | | | | |
| p. Tendon | | | | | | | | | | | | |
| q. Umbilical Cord Blood Stem Cells ☐ Autologous ☐ Family Related ☐ Allogeneic | | | | | | | | | | | | |
| r. Vascular Graft | | | | | | | | | | | | |
| s. | | | | | | | | | | | | |
| t. | | | | | | | | | | | | |
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