

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: 3000718792

**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-FEB-2006  
 PRINTED BY FDA: 01-MAR-2006  
 DISTRICT OFFICE: Cincinnati

PART I - ESTABLISHMENT INFORMATION	PART II - PRODUCT INFORMATION																																																																																															
<p><b>3. OTHER FDA REGISTRATIONS</b></p> <p>a. BLOOD FDA 2830 NO. _____</p> <p>b. DEVICES FDA 2891 NO. _____</p> <p>c. DRUG FDA 2656 NO. _____</p> <p><b>4. PHYSICAL LOCATION</b> (Include legal name, number and street, city, state, country, and post office code)</p> <p>Lions Eye Bank of Lexington                      3290 Blazer Parkway                      Suite 201                      Lexington, Kentucky 40509</p> <p>PHONE 859-323-6740 EXT _____</p> <p><b>5. ENTER CORRECTIONS TO ITEM 4</b></p> <p><b>6. MAILING ADDRESS OF REPORTING OFFICIAL</b> (Include institution name if applicable, number and street, city, state, country, and post office code)</p> <p>Lions Eye Bank of Lexington                      3290 Blazer Parkway                      Suite 201                      Lexington, Kentucky 40509</p> <p>PHONE 859-323-6740 EXT _____</p> <p><b>7. ENTER CORRECTIONS TO ITEM 6</b></p> <p><b>8. U.S. AGENT</b></p> <p>a. E-MAIL _____ b. PHONE _____</p> <p><b>9. REPORTING OFFICIAL'S SIGNATURE</b></p> <p><i>Robert A. Gayheart, CEBT</i></p> <p>a. TYPED NAME Robert A. Gayheart</p> <p>b. E-MAIL ragayh2@uky.edu</p> <p>c. TITLE CEBT d. DATE 12-DEC-2005</p>	<p><b>10. ESTABLISHMENT FUNCTIONS:</b></p> <p>a. <input checked="" type="checkbox"/> RECOVER c. <input type="checkbox"/> TEST e. <input checked="" type="checkbox"/> PROCESS g. <input checked="" type="checkbox"/> LABEL</p> <p>b. <input checked="" type="checkbox"/> SCREEN d. <input checked="" type="checkbox"/> PACKAGE f. <input checked="" type="checkbox"/> STORE h. <input checked="" type="checkbox"/> DISTRIBUTE</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 25%;">TYPES OF HCT/Ps</th> <th style="width: 15%;">11. HCT/Ps DESCRIBED IN 21 CFR 1271.10</th> <th style="width: 20%;">12. HCT/Ps REGULATED AS MEDICAL DEVICES, DRUGS, OR BIOLOGICAL DRUGS</th> <th style="width: 40%;">13. PROPRIETARY NAME(S)</th> </tr> </thead> <tbody> <tr> <td>a. Bone</td> <td></td> <td></td> <td></td> </tr> <tr> <td>b. Cartilage</td> <td></td> <td></td> <td></td> </tr> <tr> <td>c. Cornea</td> <td style="text-align: center;">X</td> <td></td> <td></td> </tr> <tr> <td>d. Dura Mater</td> <td></td> <td></td> <td></td> </tr> <tr> <td>e. Embryo</td> <td></td> <td></td> <td></td> </tr> <tr> <td>f. Fascia</td> <td></td> <td></td> <td></td> </tr> <tr> <td>g. Heart Valve</td> <td></td> <td></td> <td></td> </tr> <tr> <td>h. Ligament</td> <td></td> <td></td> <td></td> </tr> <tr> <td>i. Oocyte</td> <td></td> <td></td> <td></td> </tr> <tr> <td>j. Pericardium</td> <td></td> <td></td> <td></td> </tr> <tr> <td>k. Peripheral Blood Stem Cells</td> <td></td> <td></td> <td></td> </tr> <tr> <td>l. Sclera</td> <td style="text-align: center;">D</td> <td></td> <td></td> </tr> <tr> <td>m. Semen</td> <td></td> <td></td> <td></td> </tr> <tr> <td>n. Skin</td> <td></td> <td></td> <td></td> </tr> <tr> <td>o. Somatic Cells</td> <td></td> <td></td> <td></td> </tr> <tr> <td>p. Tendon</td> <td></td> <td></td> <td></td> </tr> <tr> <td>q. Umbilical Cord Blood Stem Cells</td> <td></td> <td></td> <td></td> </tr> <tr> <td>r. Vascular Graft</td> <td></td> <td></td> <td></td> </tr> <tr> <td>s.</td> <td></td> <td></td> <td></td> </tr> <tr> <td>t.</td> <td></td> <td></td> <td></td> </tr> <tr> <td>u.</td> <td></td> <td></td> <td></td> </tr> <tr> <td>v.</td> <td></td> <td></td> <td></td> </tr> </tbody> </table>				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	D			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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