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| 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: 3003562205 | 2. REASON FOR SUBMISSION a. <input type="checkbox"/> INITIAL REGISTRATION / LISTING b. <input checked="" type="checkbox"/> ANNUAL REGISTRATION / LISTING c. <input type="checkbox"/> CHANGE IN INFORMATION d. <input type="checkbox"/> INACTIVE | VALIDATION--FOR FDA USE ONLY VALIDATED BY FDA:28-NOV-2017 DISTRICT: New Orleans PRINTED BY FDA:27-JAN-2018 |
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| PART I - ESTABLISHMENT INFORMATION | PART II - PRODUCT INFORMATION | 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) | | | | | | | | | | | | | | | | | | | | | |
|--|---|--|---|---|-------------------------|-------------------|-------------------------|------------|--|--|--|--|--|--|--|--|--|--|---------|--------|------|---------|---------|-------|-------|------------|
| 3. OTHER FDA REGISTRATIONS a. BLOOD FDA 2830 NO. _____ b. DEVICES FDA 2891 NO. _____ c. DRUG FDA 2656 NO. _____ | 10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps <table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th rowspan="2" style="width:30%;">Types of HCT / Ps</th> <th colspan="8" style="text-align: center;">Establishment Functions</th> <th rowspan="2"></th> <th rowspan="2"></th> <th rowspan="2"></th> <th rowspan="2"></th> </tr> <tr> <th style="width:5%;">Recover</th> <th style="width:5%;">Screen</th> <th style="width:5%;">Test</th> <th style="width:5%;">Package</th> <th style="width:5%;">Process</th> <th style="width:5%;">Store</th> <th style="width:5%;">Label</th> <th style="width:5%;">Distribute</th> </tr> </thead> </table> | | | | | Types of HCT / Ps | Establishment Functions | | | | | | | | | | | | Recover | Screen | Test | Package | Process | Store | Label | Distribute |
| Types of HCT / Ps | Establishment Functions | | | | | | | | | | | | | | | | | | | | | | | | | |
| | Recover | Screen | Test | Package | Process | Store | Label | Distribute | | | | | | | | | | | | | | | | | | |
| 4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code) Alabama Eye Bank North Alabama Regional Office 250 Governors Drive Medical Hills, Suite 1 Huntsville, Alabama 35801 a. PHONE 205-313-8341 EXT _____ b. <input checked="" type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. 3001236642) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY | a. Bone b. Cartilage c. Cornea d. Dura Mater e. Embryo f. Fascia g. Heart Valve h. Ligament i. Oocyte j. Pericardium k. Peripheral Blood Stem l. Sclera m. Semen n. Skin o. Somatic Cell Therapy Products p. Tendon q. Umbilical Cord Blood r. Vascular Graft | | | | | | | | | | | | | | | | | | | | | | | | | |
| 5. ENTER CORRECTIONS TO ITEM 4 | <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous | | | | | | | | | | | | | | | | | | | | | | | | | |
| 6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code) Alabama Eye Bank Central Office Attn: Kyle L. Mavin, CEBT 500 Robert Jemison Road Birmingham, Alabama 35209 a. PHONE 205-942-2120 EXT 8334 | <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic | | | | | | | | | | | | | | | | | | | | | | | | | |
| 7. ENTER CORRECTIONS TO ITEM 6 | <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous | | | | | | | | | | | | | | | | | | | | | | | | | |
| 8. U.S. AGENT a. E-MAIL | <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic | | | | | | | | | | | | | | | | | | | | | | | | | |
| 9. REPORTING OFFICIAL'S SIGNATURE a. TYPED NAME Kyle L. Mavin, CEBT b. E-MAIL kmavin@alabamaeyebank.org c. TITLE Chief Clinical Officer d. DATE 28-NOV-2017 | s. t. u. v. | | | | | | | | | | | | | | | | | | | | | | | | | |