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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: 3008808182 | 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:15-DEC-2016 DISTRICT: Cincinnati PRINTED BY FDA:24-JAN-2017 |
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| PART I - ESTABLISHMENT INFORMATION | PART II - PRODUCT INFORMATION | | | | | | | | | | | | | | 14. PROPRIETARY NAME(S) | |
|---|--|---------|--------|------|---------|---------|-------|-------|------------|--|---|---|--|--|-------------------------|--|
| 3. OTHER FDA REGISTRATIONS | 10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps | | | | | | | | | 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 | | | | |
| | Establishment Functions | | | | | | | | | | | | | | | |
| | Types of HCT / Ps | Recover | Screen | Test | Package | Process | Store | Label | Distribute | | | | | | | |
| 4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code) Community Blood Center dba Community Tissue Services 2900 College Drive Kettering, Ohio 45420 a. PHONE 937-222-0228 EXT _____ b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY | a. Bone | | | | X | X | X | X | X | X | | | | | | |
| | b. Cartilage | | | | X | X | X | X | X | X | | | | | | |
| | c. Cornea | | | | | | | | | | | | | | | |
| | d. Dura Mater | | | | | | | | | | | | | | | |
| | e. Embryo <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous | | | | | | | | | | | | | | | |
| | f. Fascia | | | | X | X | X | X | X | X | X | | | | | |
| | g. Heart Valve | | | | | | | | | | | | | | | |
| | h. Ligament | | | | X | X | X | X | X | X | X | | | | | |
| | i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous | | | | | | | | | | | | | | | |
| | j. Pericardium | | | | X | X | X | X | X | X | X | | | | | |
| 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) Community Blood Center dba Community Tissue Services Attn: David M. Smith, MD 349 South Main Street Dayton, Ohio 45402-2715 a. PHONE 937-461-3450 EXT 3610 | k. Peripheral Blood Stem <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic | | | | | | | | | | | | | | | |
| | l. Sclera | | | | | | | | | | | | | | | |
| | m. Semen <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous | | | | | | | | | | | | | | | |
| | n. Skin | | | | X | X | X | X | X | X | X | | | | | |
| | o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic | | | | | | | | | | | | | | | |
| | p. Tendon | | | | X | X | X | X | X | X | X | | | | | |
| | q. Umbilical Cord Blood <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic | | | | | | | | | | | | | | | |
| | r. Vascular Graft | | | | | | | | | | | | | | | |
| | s. Parathyroid | | | | | | | X | | | X | X | | | | |
| | t. Peritoneal Membrane | | | | X | X | X | X | X | X | X | | | | | |
| 7. ENTER CORRECTIONS TO ITEM 6 b. PHONE _____ | u. | | | | | | | | | | | | | | | |
| | v. | | | | | | | | | | | | | | | |
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| 8. U.S. AGENT a. E-MAIL _____ | | | | | | | | | | | | | | | | |
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| 9. REPORTING OFFICIAL'S SIGNATURE a. TYPED NAME David M. Smith, MD b. E-MAIL dsmith@cbccts.org c. TITLE CEO d. DATE 14-DEC-2016 | | | | | | | | | | | | | | | | |
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