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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: 3003374197 | 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:16-NOV-2016 DISTRICT: Los Angeles PRINTED BY FDA:15-DEC-2016 |
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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 | | | | |
| | 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) Donor Network of Arizona 201 West Coolidge St Phoenix, Arizona 85013 a. PHONE 602-222-2200 EXT 2214 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 | | | | | |
| | b. Cartilage | X | X | | | | | | | | X | | | | | |
| | c. Cornea | X | X | | X | 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 | X | X | | | | | | | | | X | | | | |
| | g. Heart Valve | X | X | | | | | | | | | X | | | | |
| | h. Ligament | X | X | | | | | | | | | X | | | | |
| | i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous | | | | | | | | | | | | | | | |
| | j. Pericardium | 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) Donor Network of Arizona Attn: Richard D. Meyer, CQA,CQT 201 West Coolidge Phoenix, Arizona 85013 a. PHONE 602-222-2200 EXT 2214 | k. Peripheral Blood Stem <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic | | | | | | | | | | | | | | | |
| | l. Sclera | X | X | | X | X | X | X | X | X | | | | | | |
| | m. Semen <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous | | | | | | | | | | | | | | | |
| | n. Skin | 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 | | | | |
| | q. Umbilical Cord Blood <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic | | | | | | | | | | | | | | | |
| | r. Vascular Graft | X | X | | | | | | | | | X | | | | |
| | s. Amniotic Membrane | X | X | | | | | | | | | X | | | | |
| | t. Placenta | X | X | | | | | | | | | X | | | | |
| 7. ENTER CORRECTIONS TO ITEM 6 b. PHONE | u. Adipose Tissue | X | X | | | | | | | | X | | | | | |
| | v. | | | | | | | | | | | | | | | |
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| 8. U.S. AGENT a. E-MAIL | | | | | | | | | | | | | | | | |
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| 9. REPORTING OFFICIAL'S SIGNATURE a. TYPED NAME Richard D. Meyer, CQA,CQT b. E-MAIL dan.meyer@dnaz.org c. TITLE Director of Quality & Regulatory Affairs d. DATE 15-NOV-2016 | | | | | | | | | | | | | | | | |
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