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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) <i>(See reverse side for instructions)</i> | 1. REGISTRATION NUMBER (Field Establishment Identifier) FEI: 3005342355 | 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 * 3005342355 * VALIDATED By FDA: 12/03/07 PRINTED By FDA: 12/07/07 DISTRICT: Los Angeles |
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| PART I - ESTABLISHMENT INFORMATION | PART II - PRODUCT INFORMATION | | | | | | | | | | 11. HCT/Ps DESCRIBED IN 21 CFR 1271.19 | 12. HCT/Ps REGULATED AS MEDICAL DEVICES | 13. HCT/Ps REGULATED AS DRUGS OR BIOLOGICAL DRUGS | 14. PROPRIETARY NAME(S) | | | | |
|--|--|-------------------------|---|--|--|---|---|---|---|---------|--|---|---|-------------------------|--------|------|---------|---------|
| 3. OTHER FDA REGISTRATIONS | 10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps | | | | | | | | | | | | | | | | | |
| | Types of HCT / Ps | Establishment Functions | | | | | | | | Recover | | | | | Screen | Test | Package | Process |
| | | | | | | | | | | | | | | | | | | |
| a. BLOOD FDA 2830 NO. _____ b. DEVICES FDA 2891 NO. _____ c. DRUG FDA 2656 NO. _____ | No HCT / P Specified | | | | | | | | | | | | | | | | | |
| 4. PHYSICAL LOCATION <i>(Include legal name, number and street, city, state, country, and post office code)</i> California Cryobank, Inc. 11915 La Grange Avenue Los Angeles, California 90025-5213 a. PHONE 310-443-5244 EXT 1000 b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY 5. ENTER CORRECTIONS TO ITEM 4 6. MAILING ADDRESS OF REPORTING OFFICIAL <i>(Include institution name if applicable, number and street, city, state, country, and post office code)</i> California Cryobank, Inc. Attn: Diana C. Schillinger 11915 La Grange Avenue Los Angeles, California 90025-5213 a. PHONE 310-443-5244 EXT 1160 7. ENTER CORRECTIONS TO ITEM 6 b. PHONE _____ 8. U.S. AGENT a. E-MAIL _____ 9. REPORTING OFFICIAL'S SIGNATURE a. TYPED NAME Diana C. Schillinger b. E-MAIL dschillinger@cryobank.com c. TITLE Compliance Manager d. DATE 27-NOV-2007 | a. Bone | | | | | | | | | | | | | | | | | |
| | b. Cartilage | | | | | | | | | | | | | | | | | |
| | c. Cornea | | | | | | | | | | | | | | | | | |
| | d. Dura Mater | | | | | | | | | | | | | | | | | |
| | e. Embryo <input checked="" type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous | | | | | | | | | X | | | X | | X | | | |
| | f. Fascia | | | | | | | | | | | | | | | | | |
| | g. Heart Valve | | | | | | | | | | | | | | | | | |
| | h. Ligament | | | | | | | | | | | | | | | | | |
| | i. Oocyte <input checked="" type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous | | | | | | | | | X | | | | | X | | | |
| | j. Pericardium | | | | | | | | | | | | | | | | | |
| | k. Peripheral Blood Stem Cells <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic | | | | | | | | | | | | | | | | | |
| | l. Sclera | | | | | | | | | | | | | | | | | |
| | m. Semen <input checked="" type="checkbox"/> SIP <input checked="" type="checkbox"/> Directed <input checked="" type="checkbox"/> Anonymous | X | X | | | X | X | X | X | X | X | X | | | | | | |
| | n. Skin | | | | | | | | | | | | | | | | | |
| | o. Somatic Cells <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic | | | | | | | | | | | | | | | | | |
| p. Tendon | | | | | | | | | | | | | | | | | | |
| q. Umbilical Cord Blood Stem Cells <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic | | | | | | | | | | | | | | | | | | |
| r. Vascular Graft | | | | | | | | | | | | | | | | | | |
| s. | | | | | | | | | | | | | | | | | | |
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