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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: 3001503330 | 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:03-DEC-2016 DISTRICT: Los Angeles PRINTED BY FDA:15-DEC-2016 |
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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 | 10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps | | | | | | | | | | | | | |
| | Types of HCT / Ps | Establishment Functions | | | | | | | | | | | | |
| | | Recover | Screen | Test | Package | Process | Store | Label | Distribute | | | | | |
| a. BLOOD FDA 2830 NO. _____ b. DEVICES FDA 2891 NO. _____ c. DRUG FDA 2656 NO. _____ | a. Bone | | | | | X | X | X | X | | | | Autologous Bone | |
| | b. Cartilage | | | | | X | | X | X | | | | | |
| | c. Cornea | | | | | X | | X | X | | | | | |
| 4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code) California Transplant Services, Inc. dba SafetyGraft 5845 Owens Avenue Carlsbad, California 92008 a. PHONE 760-804-6890 EXT 101 b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY | 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 | | | | | | | | | | | | | |
| | h. Ligament | | | | | X | | X | X | | | | | |
| | i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous | | | | | | | | | | | | | |
| | j. Pericardium | | | | | | | | | | | | | |
| | k. Peripheral Blood Stem <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic | | | | | | | | | | | | | |
| | l. Sclera | | | | | | X | | X | X | | | | |
| | m. Semen <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous | | | | | | | | | | | | | |
| 5. ENTER CORRECTIONS TO ITEM 4 | n. Skin | | | | | X | | X | X | | | | Donor and Autologous Skin | |
| | o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic | | | | | | | | | | | | | |
| 6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code) California Transplant Services, Inc. dba SafetyGraft Attn: Marc Pablo, CEBT, CTBS PO Box 130815 Carlsbad, California 92013 a. PHONE 760-804-6890 EXT 101 | 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 | | | | | | | | | | | | | |
| 7. ENTER CORRECTIONS TO ITEM 6 | s. Parathyroid | | | | | X | | X | X | | | | Autologous Parathyroid | |
| | t. | | | | | | | | | | | | | |
| | u. | | | | | | | | | | | | | |
| | v. | | | | | | | | | | | | | |
| 8. U.S. AGENT a. E-MAIL | | | | | | | | | | | | | | |
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| 9. REPORTING OFFICIAL'S SIGNATURE a. TYPED NAME Marc Pablo, CEBT, CTBS b. E-MAIL mpablo@catransplant.org c. TITLE Sr. Vice President | d. DATE 02-DEC-2016 | | | | | | | | | | | | | |
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