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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: 0002476837 | 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:08-DEC-2016 DISTRICT: New York 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 |
| a. BLOOD FDA 2830 NO. FEI: 0002476837 b. DEVICES FDA 2891 NO. _____ c. DRUG FDA 2656 NO. _____ | | a. Bone | | | | | | | | | | | | | | | | | | | |
| 4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code) New York Blood Center, Inc. 310 E 67th St. New York, New York 10065 a. PHONE 212-570-3372 EXT _____ b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY | b. Cartilage | | | | | | | | | | | | | | | | | | | | |
| | c. Cornea | | | | | | | | | | | | | | | | | | | | |
| | d. Dura Mater | | | | | | | | | | | | | | | | | | | | |
| | e. Embryo <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous | | | | | | | | | | | | | | | | | | | | |
| | f. Fascia | | | | | | | | | | | | | | | | | | | | |
| | g. Heart Valve | | | | | | | | | | | | | | | | | | | | |
| | h. Ligament | | | | | | | | | | | | | | | | | | | | |
| | i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous | | | | | | | | | | | | | | | | | | | | |
| | j. Pericardium | | | | | | | | | | | | | | | | | | | | |
| | k. Peripheral Blood Stem <input checked="" type="checkbox"/> Autologous <input checked="" type="checkbox"/> Family Related <input checked="" type="checkbox"/> Allogeneic | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X |
| l. Sclera | | | | | | | | | | | | | | | | | | | | | |
| m. Semen <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous | | | | | | | | | | | | | | | | | | | | | |
| 5. ENTER CORRECTIONS TO ITEM 4 | n. Skin | | | | | | | | | | | | | | | | | | | | |
| 6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code) New York Blood Center, Inc. Attn: Christine Driscoll 1200 Prospect Avenue Westbury, New York 11590 a. PHONE 516-478-5264 EXT _____ b. PHONE _____ | o. Somatic Cell Therapy Products <input checked="" type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic | X | | | X | X | X | X | X | X | X | | | | | | | | X | | |
| | 8. U.S. AGENT | p. Tendon | | | | | | | | | | | | | | | | | | | |
| a. E-MAIL | q. Umbilical Cord Blood <input checked="" type="checkbox"/> Autologous <input checked="" type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic | | | X | X | X | X | X | X | | X | | | | | | | | | | |
| | 9. REPORTING OFFICIAL'S SIGNATURE | r. Vascular Graft | | | | | | | | | | | | | | | | | | | |
| a. TYPED NAME Christine Driscoll b. E-MAIL cdriscoll@nybc.org c. TITLE Director, Regulatory Affairs d. DATE 07-DEC-2016 | s. Parathyroid | | | X | X | X | X | X | X | X | X | | | | | | | | | | |
| | t. Therapeutic Cells | X | | X | X | X | X | X | X | X | X | | | | | | | | | | |
| | u. | | | | | | | | | | | | | | | | | | | | |
| | v. | | | | | | | | | | | | | | | | | | | | |