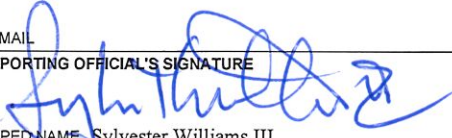


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| DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/Ps) (See reverse side for instructions) | 1. REGISTRATION NUMBER (FDA Establishment Identifier) FEI: 3002199759 | 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: 23-NOV-2016 DISTRICT: Minneapolis PRINTED BY FDA: 16-DEC-2016 |
|---|--|--|--|

| PART I - ESTABLISHMENT INFORMATION | PART II - PRODUCT INFORMATION | | | | | | | | | | 11. HCT/Ps REGULATED IN 21 CFR 1271.10 | 12. HCT/Ps REGULATED AS MEDICAL DEVICES | 13. HCT/Ps REGULATED AS BIOLOGICAL DRUGS | 14. PROPRIETARY NAME(S) | | | | |
|---|--|--------|------|---------|---------|-------|-------|------------|-------------------|--|--|---|--|-------------------------|--|--|---|--|
| 3. OTHER FDA REGISTRATIONS | 10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps | | | | | | | | | | | | | | | | | |
| | Establishment Functions | | | | | | | | Types of HCT / Ps | | | | | | | | | |
| | Recover | Screen | Test | Package | Process | Store | Label | Distribute | | | | | | | | | | |
| a. BLOOD FDA 2830 NO. _____ | | | | | | | | | | | | | | | | | | |
| b. DEVICES FDA 2891 NO. FEI: 3002199759 | | | | | | | | | | | | | | | | | | |
| c. DRUG FDA 2656 NO. FEI: 3002199759 | | | | | | | | | | | | | | | | | | |
| 4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code) WuXi AppTec Inc. 2540 Executive Drive St. Paul, Minnesota 55120 a. PHONE 651-675-2000 EXT 2055 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 | |
| | 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 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 | | | | | | | | | | | | | | | | | |
| | o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic | | | | | | | | | | | | | | | | | |
| | p. Tendon | | | | | | | | | | | | | | | | | |
| | q. Umbilical Cord Blood <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic | | | | | | | | | | | | | | | | | |
| | r. Vascular Graft | | | | | | | | | | | | | | | | | |
| | s. | | | | | | | | | | | | | | | | | |
| | t. | | | | | | | | | | | | | | | | | |
| | u. | | | | | | | | | | | | | | | | | |
| | v. | | | | | | | | | | | | | | | | | |
| 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) WuXi AppTec Inc. Attn: Sylvester Williams III 2540 Executive Drive St. Paul, Minnesota 55120 a. PHONE 651-675-2000 EXT 2055 | | | | | | | | | | | | | | | | | | |
| 7. ENTER CORRECTIONS TO ITEM 6 b. PHONE | | | | | | | | | | | | | | | | | | |
| 8. U.S. AGENT | | | | | | | | | | | | | | | | | | |
| a. E-MAIL | | | | | | | | | | | | | | | | | | |
| 9. REPORTING OFFICIAL'S SIGNATURE  | | | | | | | | | | | | | | | | | | |
| a. TYPED NAME Sylvester Williams III | | | | | | | | | | | | | | | | | | |
| b. E-MAIL sylvester.williams@wuxiapptec.com | | | | | | | | | | | | | | | | | | |
| c. TITLE Director Regulatory Affairs | | | | | | | | | | | | | | | | | | |
| d. DATE 22-NOV-2016 | | | | | | | | | | | | | | | | | | |