See Instructions for OMB Statement FORM APPROVED: OMB No. 0910-0543. Expiration Date: 1/31/14

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
(Field Establishment Identifier)

FEI: 0001061168

2. REASON FOR SUBMISSION

a. [ ] INITIAL REGISTRATION / LISTING
b. [X] ANNUAL REGISTRATION / LISTING
c. [ ] CHANGE IN INFORMATION
d. [ ] INACTIVE

VALIDATION--FOR FDA USE ONLY 1
VALIDATED BY FDA:14-DEC-2011
DISTRICT: Atlanta
PRINTED BY FDA:15-DEC-2011

PART I - ESTABLISHMENT INFORMATION

3. OTHER FDA REGISTRATIONS

a. BLOOD FDA 2830 NO.
b. DEVICES FDA 2891 NO.
c. DRUG FDA 2656 NO. FEI: 1000511606

4. PHYSICAL LOCATION *(Include legal name, number and street, city, state, country, and post office code)*

WuXi Apptec, Inc.
1265 Kennestone Circle
Marietta, Georgia 30066

a. PHONE 770-514-0262 EXT
b. [ ] SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO.
c. [X] TESTING FOR MICRO-ORGANISMS ONLY

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: Ginger Lane
1265 Kennestone Circle
Marietta, Georgia 30066

a. PHONE 770-514-0262 EXT 2223

7. ENTER CORRECTIONS TO ITEM 6 b. PHONE

8. U.S. AGENT

a. E-MAIL

9. REPORTING OFFICIAL'S SIGNATURE

Ginger Lane 12-16-11

a. TYPED NAME Ginger Lane
b. E-MAIL ginger.lane@wuxiapptec.com
c. TITLE QA Director d. DATE 13-DEC-2011

PART II - PRODUCT INFORMATION

10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps

Types of HCT / Ps	Establishment Functions: Recover	Screen	Test	Package	Process	Store	Label	Distribute	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)
a. Bone			X						X	X		
b. Cartilage			X						X			
c. Cornea												
d. Dura Mater												
e. Embryo [ ] SIP [ ] Directed [ ] Anonymous									D			
f. Fascia			X						X			
g. Heart Valve												
h. Ligament			X						X			
i. Oocyte [ ] SIP [ ] Directed [ ] Anonymous												
j. Pericardium			X						X			
k. Peripheral Blood Stem Cells [ ] Autologous [ ] Family Related [ ] Allogeneic												
l. Sclera												
m. Semen [ ] SIP [ ] Directed [ ] Anonymous												
n. Skin			X						X	D		
o. Somatic Cell Therapy Products [ ] Autologous [ ] Family Related [X] Allogeneic			X								X	
p. Tendon			X						X			
q. Umbilical Cord Blood Stem Cells [ ] Autologous [ ] Family Related [X] Allogeneic			X						X		X	
r. Vascular Graft			X						X			
s.												
t.												
u.												
v.												