

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: 3000719146

2. REASON FOR SUBMISSION
a. INITIAL REGISTRATION / LISTING
b. ANNUAL REGISTRATION / LISTING
c. CHANGE IN INFORMATION
d. INACTIVE

VALIDATION--FOR FDA USE ONLY
VALIDATED BY FDA:23-DEC-2016
DISTRICT: Denver
PRINTED BY FDA:03-JAN-2017

PART I - ESTABLISHMENT INFORMATION
3. OTHER FDA REGISTRATIONS
a. BLOOD FDA 2830 NO. _____
b. DEVICES FDA 2891 NO. _____
c. DRUG FDA 2656 NO. _____

4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code)
ClinImmune Labs-Univ Colorado Cord Blood Bank and Stem Cell Laboratory
12705 E. Montview Boulevard
Suite 250
Aurora, Colorado 80045

a. PHONE 303-724-0535 EXT _____
b. SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____)
c. TESTING FOR MICRO-ORGANISMS ONLY

5. ENTER CORRECTIONS TO ITEM 4

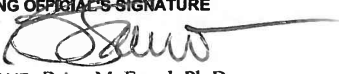
6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code)
ClinImmune Labs-Univ Colorado Cord Blood Bank and Stem Cell Laboratory
Attn: Brian M. Freed, Ph.D.
12705 E. Montview Boulevard
Suite 250
Aurora, Colorado 80045

a. PHONE 303-724-0535 EXT _____

7. ENTER CORRECTIONS TO ITEM 6 b. PHONE _____

8. U.S. AGENT

a. E-MAIL _____

9. REPORTING OFFICIAL'S SIGNATURE

a. TYPED NAME Brian M. Freed, Ph.D.
b. E-MAIL brian.freed@ucdenver.edu
c. TITLE Executive Director
d. DATE 22-DEC-2016

10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps	Establishment Functions									11. HCTPs DESCRIBED IN 21 CFR 1271.10	12. HCTPs REGULATED AS MEDICAL DEVICES	13. HCTPs REGULATED AS DRUGS OR BIOLOGICAL DRUGS	14. PROPRIETARY NAME(S)
	Recover	Screen	Test	Package	Process	Store	Label	Distribute					
a. Bone													
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	
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 checked="" type="checkbox"/> Autologous <input checked="" type="checkbox"/> Family Related <input checked="" type="checkbox"/> Allogeneic	X	X			X	X	X	X	X	X		X	
r. Vascular Graft													
s. Parathyroid					X	X	X	X	X	X			
t. Umbilical Cord		X	X		X	X	X	X	X	X			
u.													
v.													