

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: Denver
DISTRICT: Denver
PRINTED BY: FDA-27-JAN-2018

PART I - ESTABLISHMENT INFORMATION

3. OTHER FDA REGISTRATIONS
a. BLOOD FDA 2830 NO.
b. DEVICES FDA 2891 NO.
c. DRUG FDA 2856 NO.

4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code)
ClimImmune 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)
ClimImmune 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 SIGNATURE
b. TYPED NAME Brian M. Freed, Ph.D.
c. E-MAIL brian.freed@unccdenverver.edu
d. DATE 19-DEC-2017

PART II - PRODUCT INFORMATION

10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps

Types of HCT / Ps	Establishment Functions						11 HCT/PS DESCRIBED IN CFR 1271.10	12 HCT/PS REGULATED AS MEDICAL DEVICES	13 HCT/PS REGULATED AS DRUGS OR BIOLOGICAL DRUGS	14 PROPRIETARY NAME(S)
	Recover	Screen	Test	Package	Process	Store				
a. Bone										
b. Cartilage										
c. Cornea										
d. Dura Mater										
e. Embryo										
f. Fascia										
g. Heart Valve										
h. Ligament										
i. Oocyte										
j. Pericardium										
k. Peripheral Blood Stem										
l. Sclera										
m. Semen										
n. Skin										
o. Somatic Cell Therapy Products										
p. Tendon										
q. Umbilical Cord Blood										
r. Vascular Graft										
s. Parathyroid										
t. Umbilical Cord										
u.										
v.										