See Instructions for OMB Statement. FORM APPROVED OMB No.0910-0543. Expiration Date: 6/30/2020

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: 3008307571

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-FEB-2018
DISTRICT: New Jersey
PRINTED BY FDA 21-MAY-2018

PART I - ESTABLISHMENT INFORMATION

3. OTHER FDA REGISTRATIONS
a BLOOD FDA 2830 NO.
b DEVICES FDA 2891 NO. FEI: 0001647098
c DRUG FDA 2656 NO.

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

220 Evans Way
Branchburg, New Jersey 08876

a PHONE 908-947-1100 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)
LifeCell Corporation, an Allergan Affiliate
Attn: Christopher Belle,
One Millennium Way
Branchburg, New Jersey 08876

a. PHONE 908-947-1100 EXT

7. ENTER CORRECTIONS TO ITEM 6 b. PHONE

8. U.S. AGENT

a E-MAIL

9. REPORTING OFFICIAL'S SIGNATURE

a TYPED NAME Christopher Belle,
b E-MAIL Christopher.Belle@allergan.com
c TITLE Exec Dir, Quality, Strategic Compliance d DATE 22-FEB-2018

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 BIOLOGICAL DRUGS	14. PROPRIETARY NAME(S)
a Bone												
b Cartilage												
c Cornea												
d Dura Mater												
e Embryo ☐ SIP ☐ Directed ☐ Anonymous												
f Fascia												
g Heart Valve												
h Ligament												
i Oocyte ☐ SIP ☐ Directed ☐ Anonymous												
j Pericardium												
k Peripheral Blood Stem ☐ Autologous ☐ Family Related ☐ Allogeneic												
l Sclera												
m Semen ☐ SIP ☐ Directed ☐ Anonymous												
n Skin				X		X	X	X	X			*** See full text on next page
o Somatic Cell Therapy Products ☐ Autologous ☐ Family Related ☐ Allogeneic												
p Tendon												
q Umbilical Cord Blood ☐ Autologous ☐ Family Related ☐ Allogeneic												
r Vascular Graft												
s												
t												
u												
v												

FORM FDA - 3356 (7/17)

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: 3008307571

2

ADDITIONAL INFORMATION:

ALLODERM SELECT RTU, ALLODERM SELECT DUO RTM, CYMETRA MIRCONIZED ALLODERM Tissue, AlloDerm GRB, Repliform, GraftJacket Xpress, ALLODERM SELECT RESTORE RTM, ALLODERM SELECT RESTORE DUO RTM

As of January 31, 2017, LifeCell Corporation is now owned by and considered an affiliate of Allergan.

Proprietary Name(s):

n. Skin See additional information for proprietary names

See Instructions for OMB Statement. FORM APPROVED OMB No 0910-0543. Expiration Date: 6/30/2020

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: 1000306051

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

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PART I - ESTABLISHMENT INFORMATION

3. OTHER FDA REGISTRATIONS
a. BLOOD FDA 2830 NO.
b. DEVICES FDA 2891 NO. FEI: 0001647098
c. DRUG FDA 2656 NO.

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

One Millennium Way
Branchburg, New Jersey 08876

a. PHONE 908-947-1100 EXT
b. ☐ SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____)
c. ☐ TESTING FOR MICRO-ORGANISMS ONLY

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Attn: Christopher Belle,
One Millennium Way
Branchburg, New Jersey 08876

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b. PHONE

7. ENTER CORRECTIONS TO ITEM 6

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a. E-MAIL

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a. TYPED NAME Christopher Belle,
b. E-MAIL Christopher.Belle@allergan.com
c. TITLE Exec Dir, Quality, Strategic Compliance d. DATE 22-FEB-2018

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h. Ligament												
i. Oocyte ☐ SIP ☐ Directed ☐ Anonymous												
j. Pericardium												
k. Peripheral Blood Stem ☐ Autologous ☐ Family Related ☐ Allogeneic												
l. Sclera												
m. Semen ☐ SIP ☐ Directed ☐ Anonymous												
n. Skin		X		X	X	X	X	X	X			*** See full text on next page
o. Somatic Cell Therapy Products ☐ Autologous ☐ Family Related ☐ Allogeneic												
p. Tendon												
q. Umbilical Cord Blood ☐ Autologous ☐ Family Related ☐ Allogeneic												
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t.												
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