See Instructions for OMB Statement

FORM APPROVED: OMB No. 0910-0543. Expiration Date: 7/31/10

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: 3005168462

2. REASON FOR SUBMISSION

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

VALIDATION--FOR FDA USE ONLY 1

3005168462

VALIDATED By FDA: 11/30/07 **PRINTED By FDA:** 11/30/07

DISTRICT: Seattle

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)*

Bacterin International Inc. Biologics Division
600 Cruiser LAne
Belgrade, Montana 59714

a. PHONE 406-388-0480 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)*

Bacterin
Attn: Robin Sullivan, DC, CTBS
600 Cruiser Lane
Belgrade, Montana 59714

a. PHONE 406-388-0480 EXT

7. ENTER CORRECTIONS TO ITEM 6 b. PHONE

8. U.S. AGENT

a. E-MAIL

9. REPORTING OFFICIAL'S SIGNATURE

a. TYPED NAME Robin Sullivan, DC, CTBS

b. E-MAIL RSullivan@bacterin.com

c. TITLE Director of QA d. DATE 15-NOV-2007

PART II - PRODUCT INFORMATION

10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps

Types of HCT / Ps	*Establishment Functions*								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)
	Recover	Screen	Test	Package	Process	Store	Label	Distribute				
No HCT / P Specified												
a. Bone		X		X	X	X	X	X	X			
b. Cartilage		X		X	X	X	X	X	X			
c. Cornea												
d. Dura Mater												
e. Embryo ☐ SIP ☐ Directed ☐ Anonymous												
f. Fascia		X		X	X	X	X	X	X			
g. Heart Valve												
h. Ligament		X		X	X	X	X	X	X			
i. Oocyte ☐ SIP ☐ Directed ☐ Anonymous												
j. Pericardium		X		X	X	X	X	X	X			
k. Peripheral Blood Stem Cells ☐ Autologous ☐ Family Related ☐ Allogeneic												
l. Sclera												
m. Semen ☐ SIP ☐ Directed ☐ Anonymous												
n. Skin												
o. Somatic Cells ☐ Autologous ☐ Family Related ☐ Allogeneic												
p. Tendon		X		X	X	X	X	X	X			
q. Umbilical Cord Blood Stem Cells ☐ Autologous ☐ Family Related ☐ Allogeneic												
r. Vascular Graft												
s.												
t.												
u.												
v.												

FORM FDA 3356 (9/07) PREVIOUS EDITION IS OBSOLETE.