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: 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
VALIDATED BY FDA:21-NOV-2017
DISTRICT: Seattle
PRINTED BY FDA:27-JAN-2018

PART I - ESTABLISHMENT INFORMATION

3. OTHER FDA REGISTRATIONS

a. BLOOD FDA 2830 NO.
b. DEVICES FDA 2891 NO. FEI: 3005168462
c. DRUG FDA 2656 NO.

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

Bacterin International Inc.

600 Cruiser Lane
Belgrade, Montana 59714

a. PHONE 406-388-0480 EXT 1128
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 International, Inc.
Attn: Casey M. Ming, CTBS
600 Cruiser Lane
Belgrade, Montana 59714

a. PHONE 406.388.0480 EXT 1128

7. ENTER CORRECTIONS TO ITEM 6 b. PHONE

8. U.S. AGENT

a. E-MAIL

9. REPORTING OFFICIAL'S SIGNATURE

a. TYPED NAME Casey M. Ming, CTBS
b. E-MAIL cming@xtantmedical.com
c. TITLE Regulatory Affairs Director d. DATE 21-NOV-2017

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	X	X	X	X	X		*** See full text on next page
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			hMatrix
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 ☐ Autologous ☐ Family Related ☐ Allogeneic												
l. Sclera												
m. Semen ☐ SIP ☐ Directed ☐ Anonymous												
n. Skin		X		X	X	X	X	X	X			hMatrix Dermis, hMatrix PR
o. Somatic Cell Therapy Products ☐ Autologous ☐ Family Related ☒ Allogeneic						X		X	X			OsteoVive
p. Tendon		X		X	X	X	X	X	X			SportMatrix
q. Umbilical Cord Blood ☐ Autologous ☐ Family Related ☐ Allogeneic												
r. Vascular Graft												
s. Placenta						X		X	X			
t.												
u.												
v.												

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ADDITIONAL INFORMATION:

Proprietary Name(s):

a. Bone — OsteoSponge, OsteoSelect DBM Putty (and Plus), OsteoWrap, Orbital Wrap HD, OsteoLock, BacFast HD, OsteoSTX, 3Demin

Notice Regarding Expiration Date on Form FDA 3356
June 6, 2017

Form FDA 3356 is currently used by establishments to register and list their products in accordance with FDA regulations (21 CFR 1271.21). The expiration date that appears in the upper right corner of form 3356 is a date the agency uses to manage its forms, and does not relate to an establishment's registration expiration. As explained on FDA's Basics for Industry webpage, on occasion, forms currently in use by FDA reach their expiration dates. FDA staff work with OMB to update and renew the expired form(s) for posting on the agency's web site for FDA Forms. The forms posted on this site may be used during this time of update and renewal.

Additional Background Information

The Paperwork Reduction Act (PRA) of 1995 requires U.S. federal government agencies to obtain Office of Management and Budget (OMB) approval before requesting or collecting most types of information from the public. Forms used by government to collect such information are approved and include an OMB assigned control number with an expiration date.

The PRA requirements apply to the collection of HCT/P establishment registration and listing information. On Form FDA 3356, the OMB control number and the expiration date of the form appear in the upper right corner of the first page. This expiration date **does not** reflect the expiration date of an HCT/P establishment's registration and listing with the FDA. On Form FDA 3356, the FDA registration validation date is listed in the "Validation – For FDA Use Only" box, in the upper right corner and it is valid for that year.

Electronic Human Cell and Tissue Establishment Registration (eHCTERS)

Members of the public may visit Human Cell and Tissue Establishment Registration (HCTERS) Public Query web page to obtain the most recent, up-to-date information about an establishment's annual registration. For example, if the last annual registration year is listed as 2017, it means that the establishment's registration is valid through December 31, 2017. If the query's report for an establishment shows a year earlier than 2017, the registration is only valid for the year indicated.

On August 31, 2016, FDA published a final rule titled, "Requirements for Foreign and Domestic Establishment Registration and Listing for Human Drugs, Including Drugs That Are Regulated Under a Biologics License Application, and Animal Drugs." There are a few changes in this new rule that apply to HCT/Ps, including the requirement for establishments to use the electronic registration system for submission of registration information, unless waived in certain circumstances. The effective date for this new rule was November 29, 2016, and the compliance deadline is set for one year after the effective date. Therefore, after November 29, 2017, Form FDA 3356 will no longer be used. The Agency is currently in the process of modifying the electronic system for human cell and tissue establishment registration and listing and will be communicating changes to all stakeholders.

Submit questions to the Tissue Registration Coordinator (tissuereg@fda.hhs.gov).