

Biocompatibles, Inc.
115 Hurley Road
Building 3
Oxford
Connecticut
06478
USA

Tel: +1 203 262 4198
Fax: +1 203 262 6314



P-7

September 18, 2013

Attention: Thomas Thompson
Senior Health Physicist
U.S. NRC Region I
2100 Renaissance Blvd., Suite 100
King of Prussia, PA 19406-2713

REC'D 09/19/13 PM 10:24

Re: **Request for NRC Consent to Transfer:**
(1) License Number 06-30764-02MD; Reference Number 030-36179
(2) License Number 06-30764-01; Reference Number 030-36099
(3) Sealed Source Device Registration Number NR-1289-S-101-S

Dear Mr. Thompson:

Pursuant to Section 184 of the Atomic Energy Act of 1954 as amended and 10 CFR § 30.34(b) and Consolidated Guidance About Materials Licenses: Guidance About Changes of Control and About Bankruptcy Involving Byproduct, Source, or Special Nuclear Materials Licenses (NUREG-1556, Volume 15), we write to request the written consent of NRC to the direct transfer of control of the above-referenced licenses (the "**Licenses**", see References (1) and (2)) from Biocompatibles, Inc. ("**Biocompatibles**") to Eckert & Ziegler BEBIG, Inc. ("**EZB**") (the "**Proposed Transfer**"). As part of the Proposed Transfer, we are also requesting NRC approval to transfer Sealed Source Device Registration (SSDR) No. NR-1289-S-101-S (Reference (3)) pursuant to NRC guidance in Volume 3, Rev. 1 of NUREG-1556, Section 13.6.

Written consent by NRC to the Proposed Transfer of the Licenses and SSDR is being requested in connection with the acquisition by EZB of the assets of Biocompatibles' brachytherapy business focused on low dose rate brachytherapy products, as well as other non-radioactive products (the "**Business**"). Biocompatibles and EZB expect to finalize EZB's acquisition of the Business within thirty (30) days of the date of this letter and respectfully request NRC's cooperation toward providing its written consent and approval within that timeframe.



I. **Consent to License Transfers**

A. Description of Transaction

Biocompatibles, Inc. is a corporation formed in the State of Delaware and is a wholly-owned subsidiary of Biocompatibles International Ltd., whose parent is BTG plc, a publicly listed company on the London Stock Exchange.

EZB is a corporation duly formed in the State of Georgia and is a wholly-owned subsidiary of Eckert & Ziegler BEBIG s.a., which is a leader in brachytherapy in Europe and headquartered in Belgium. Eckert & Ziegler BEBIG s.a. has been listed on the NYSE Euronext stock exchange in Brussels since April 1997 and is registered with the Financial Services and Markets Authority in Belgium.

The new name of the licensed entity after the transaction will be Eckert & Ziegler BEBIG, Inc., and an administrative license amendment will be needed to effect the name change, to be effective on the closing date of the transaction, which will be within the next thirty (30) days. The facility is located at 115 Hurley Road, Building 3, Oxford, Connecticut 06478, and the Radiation Safety Officer (RSO) remains the same (Wayne Richardson). The contact person on the license continues to be the RSO. A pre-closing and post-closing organizational chart is enclosed for your reference.

B. Personnel, Facilities, Procedures, Equipment

The Licenses are currently associated with Biocompatibles' location at 115 Hurley Road, Building 3, Oxford, Connecticut. The Proposed Transfer contemplates the Business remaining at the same location, with the individuals responsible for management of the site also remaining the same. No changes to the facilities, procedures, equipment or authorized users having control over licensed activities at the site will occur as a result of the Proposed Transfer. EZB will not make changes in the use, possession, location or storage of licensed materials. The mailing address of the location will change to 115 Hurley Road, Building 3A, but no characteristic of the physical location will otherwise change.

C. Surveillance Program

The surveillance program and records for the Oxford facility are, and will remain, current at the time of transfer. All required surveillances have been performed and documented. EZB will assume possession and maintain all records pertaining to licensed material surveillance and no change in committed requirements will be made.

D. Decommissioning and Related Records Transfers

The transferee hereby agrees to maintain such records received from the transferor in accordance with NRC requirements and no decommissioning at the site will be required.



E. Transferee's Commitment

In contemplation of the Proposed Transfer, EZB acknowledges and agrees that it will abide by all constraints, conditions, requirements, representations and commitments made to NRC by Biocompatibles, including any open inspection items, and that it will adhere to all NRC requirements and responsibilities with respect thereto.

II. **Sealed Source Device Registration Transfer Approval**

As noted above, Biocompatibles, Inc., the current licensee, is the holder of SSDR No. NR-1289-S-101-S.

It is Biocompatibles' understanding that NRC is currently reviewing Biocompatibles' SSDR to ascertain whether or not it is required for operating the Business. To the extent NRC determines that the SSDR is required for operation of the business, both Biocompatibles and EZB also hereby request approval by NRC to transfer the SSDR along with the Licenses.

When the holder of an SSDR certificate requests that it be transferred due to an ownership change, under NRC guidance (NUREG-1556, Vol. 3., Rev. 1, Section 13.6), the following information is provided:

- A. The facility's name will be Eckert & Ziegler BEBIG, Inc. The location of use will not change, although the facility mailing address will change to 115 Hurley Road, Building 3A.
- B. Biocompatibles assigns serial numbers upon receipt of order, not according to manufacturing or shipping sequences. Biocompatibles' last shipment date was May 1, 2013 under airbill number 5214 8802 3804.
- C. No products are being transferred to the proposed new SSDR certificate holder. The transferee will assume responsibility for records custody and servicing arrangements, if any, for products previously distributed.
- D. A sample new label is enclosed, and will be included with any brachytherapy products distributed by EZB to customers.
- E. No changes have been made to the products covered by the SSDR since its last amendment.
- F. There are no changes to previous commitments made by the current SSDR certificate holder.
- G. There will be no changes to the radiation safety based quality assurance program as a result of the requested transfer of the SSDR certificate.



Please do not hesitate to contact either EZB or Biocompatibles if the NRC will require any additional information in order to provide the requested written consent to the Proposed Transfer.

Thank you.

Yours sincerely,

Biocompatibles, Inc.

A handwritten signature in black ink, appearing to read "J. Matons".

James Matons, President
115 Hurley Road, Building 3, Oxford,
Connecticut 06478
Direct: +1 203 262 4198 Ext 3107
Mobile: +1 215 407 3767
Email: james.matons@biocompatibles.com

Eckert & Ziegler BEBIG Inc.

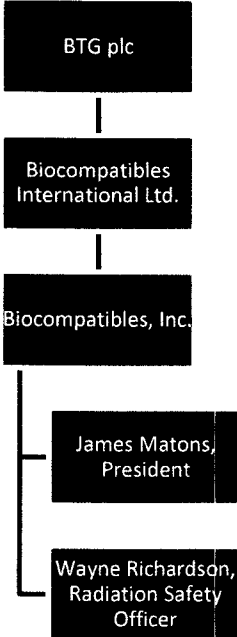
A handwritten signature in black ink, appearing to read "Bill Dowd".

Bill Dowd, COO
115 Hurley Road, Building 3A, Oxford,
Connecticut
06478
Direct: + 1 203 262 0571
Mobile: + 1 443 538 6017
Email: bill.dowd@bebig.com

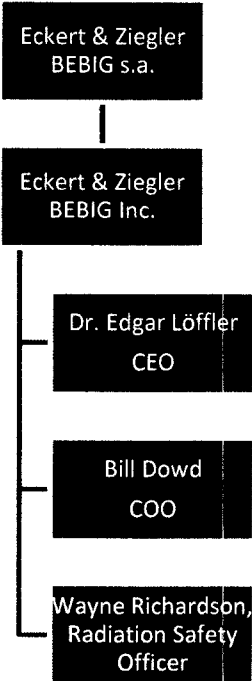
A handwritten signature in black ink, appearing to read "Wayne Richardson".

Wayne Richardson, RSO
115 Hurley Road, Building 3A, Oxford,
Connecticut
06478
Direct: + 1 203 262 0571 Ext 3105
Mobile: + 1 203 910 1286
Email: wayne.richardson@bebig.com

Pre-Transfer Organizational Chart



Post-Transfer Organizational Chart





Eckert & Ziegler BEBIG, Inc. 115 Hurley Road, Bldg 3A Oxford, CT 06478
Tel: 203-262-4571 Fax: 203-262-4198

ENGLISH

LOT #

Product Name Tray 1 of 1

Sterile/Stérile Single Patient Use

Seed Manufacturer: (Select one)

Isotope: (Select one) 2013-

Reference Date:

Total Sources: No. of Magazines:

Apparent Average Activity: mCi $\mu\text{Gym}^2/\text{h}$

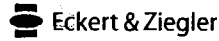
Total Apparent Activity: mCi $\mu\text{Gym}^2/\text{h}$



Caution: Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.

TRAY LABEL

AS-APP REV (Draft)



Eckert & Ziegler BEBIG, Inc. 115 Hurley Road, Bldg 3A Oxford, CT 06478
Tel: 203-262-4571 Fax: 203-262-4198

ENGLISH

LOT #

Product Name Pouch 1 of 1

Sterile/Stérile Single Patient Use

Seed Manufacturer: (Select one)

Isotope: (Select one) 2013-

Reference Date:

Total Sources: No. of Magazines:

Apparent Average Activity: mCi $\mu\text{Gym}^2/\text{h}$

Total Apparent Activity: mCi $\mu\text{Gym}^2/\text{h}$



Caution: Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.

POUCH LABEL

AS-APP REV (Draft)