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May 15, 2017

Division of Nuclear Materials Safety  
U.S. Nuclear Regulatory Commission, Region I  
2100 Renaissance Blvd, Suite 100  
King of Prussia, PA 19406-2713

Materials Licensing Branch  
U.S. Nuclear Regulatory Commission, Region III  
2443 Warrenville Road, Suite 210  
Lisle, IL 60532-4352

REC RC 10522117M1047

**Re: Request for Written Consent to Indirect Changes of Control Pursuant to 10 CFR § 30.34(b) - Zevacor Pharma, Inc.**

(1) NRC License No. 45-25221-05


(2) NRC License No. 45-25221-01MD *103 032974*

To Whom It May Concern:

Zevacor Pharma, Inc. ("Zevacor") hereby requests that the NRC grant written consent to the indirect change of control of the materials licenses listed above. Zevacor is currently licensed under license (1) above for Kansas City, Missouri, and separately under license (2) for Morgantown, West Virginia, and the Kansas City, Missouri site. These licenses authorize the production and distribution of various radioactive materials, which are primarily distributed to medical use licensees.

Please note that materials license (2) (45-25221-01MD) covers two facilities under NRC jurisdiction: Morgantown, West Virginia, and Kansas City, Missouri. The Kansas City facility is also covered under NRC materials license (1) above (45-25221-05), administered through NRC Region III. As such, duplicate NRC consent requests are being sent to both Region I and Region III offices. We respectfully request that these requests be coordinated between the two Regional offices.

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The parties to the planned transaction that is the basis for these consent requests intend to close the transaction no later than August 3, 2017. Accordingly, we respectfully request that the NRC perform a prompt review of these requests so that the transaction can close in a timely manner.

Please find below the information identified in NRC NUREG-1556, Volume 15, Sections 5.1-5.6:

### **5.1 Description of the Transaction**

- A. The NRC licensee for both referenced NRC licenses is Zevacor Pharma, Inc. or "Zevacor," a Virginia corporation. Zevacor is currently a wholly-owned subsidiary of GRD US PET Operations, Inc. ("GRD"), a Delaware corporation. The pending change of ownership will occur via a stock transfer transaction whereby C-Molecular, Inc. is selling 100% of the stock of GRD US PET Operations to Sofie Network, Inc. Prior to the transaction, GRD US PET Operations wholly owns Zevacor Pharma, Inc., which operates the facility. Once the transaction is complete, Sofie Network, Inc. will wholly own GRD US PET Operations. GRD will continue to wholly own Zevacor post-closing. Zevacor will *remain* the NRC licensee under both NRC licenses. The current and planned (post-closing) corporate structures are below:



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- B. Personnel named in the above-referenced licenses, personnel qualifications, and training programs will not change. There will be no change in corporate personnel having control of licensed facilities; however, an additional corporate management position of Director of Radiation Compliance and Environmental Health & Safety has been added to the organization, reporting to Ms. Jill Wilson, the Interim Head of QA/RA/EHS. Ms. Wilson has assumed the role formerly held by Todd Hockemeyer. The Director of Radiation Compliance and Environmental Health & Safety is Mr. Frank Plastini (resume attached). Please address future correspondence regarding this license to Mr. Plastini's attention at 21000 Atlantic Blvd., Suite 730, Dulles, VA 20166; or via email to [regulatoryaffairs@zevacor.com](mailto:regulatoryaffairs@zevacor.com).

## 5.2 Changes of Personnel

- A. No new individuals having control over licensed activities at any location (*i.e.*, authorized users or authorized nuclear pharmacists) will be added as a result of the planned transaction.
- B. There will be no change in the Radiation Safety Officer (RSO) at any location. The RSO for License No. 45-25221-01MD will remain Mr. Michael A. Levy. The RSO for License No. 45-25221-05 will remain Mr. Todd Heiskell.

## 5.3 Changes of Location, Equipment or Procedures

- A. No changes are planned at any location in the organization that exercises control over licensed material as a result of the transaction.



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- B. There will be no changes in the place of use of licensed materials at any location as a result of the transaction.
- C. There will be no changes to the facilities where licensed materials are used at any location as a result of the transaction.
- D. There will be no changes to the equipment associated with the use of licensed material at any location as a result of the planned transaction.
- E. There will be no changes to procedures associated with the licensed materials at any location as a result of the transaction.
- F. There will be no additional authorized users or authorized nuclear pharmacists added to the license or changes to the license RSO as a result of this transaction.

#### **5.4 Surveillance Records**

- A. All required surveillance activities have been performed, documented and reviewed at each of the locations. The surveillance programs are current and will remain current at the time of the transfers.

#### **5.5 Decommissioning and Related Records Transfers**

- A. Since there are no changes to the facilities, equipment, or storage location of records as a result of the transaction, required records will continue to remain available at the sites (*i.e.*, current locations of use).
- B. Zevacor commits to continue to maintain the applicable records.
- C. Contamination and ambient radiation levels at the referenced facilities are consistent with those expected at operating facilities that produce and distribute the types and



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quantities of radioactive materials that are handled at these sites. Contamination and ambient radiation levels are in compliance with the regulations and license requirements.

- D. There will not be any decontamination to prepare the facilities for decommissioning prior to the change of control.
- E. Decommissioning of the Kansas City and WVU sites is not planned at this time, *i.e.*, it is the intent to continue to operate these sites for the foreseeable future following the change of control. Contamination levels, including activation products, are consistent with those expected at facilities that produce and distribute the types and quantities of radioactive materials that are handled at these sites. Contamination and ambient radiation levels are in compliance with the regulations and license requirements. Zevacor is knowledgeable of the extent and levels of contamination and applicable decommissioning requirements.
- F. Zevacor continues to accept full responsibility for decommissioning under both Licenses, including any contaminated facilities and equipment, post-transfer of control.
- G. Operations at the Kansas City and WVU facilities will continue during the transfer process.

#### 5.6 Transferee's Commitment to Abide by the Transferor's Commitments

- A. As the continuing holder of the NRC Licenses, Zevacor continues to agree to abide by all constraints, license conditions, requirements, representations and commitments identified in and attributed thereto.



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B. At this time there are no open inspection or enforcement issues at any location.

We appreciate your assistance with this transaction. Please contact Jill Wilson at [REDACTED]  
Frank Plastini at (518) 357-8645 (office) [REDACTED] or via email to  
[regulatoryaffairs@zevacor.com](mailto:regulatoryaffairs@zevacor.com) with any questions regarding this issue.

Sincerely,

Timothy D. Stone, Jr.  
President & CEO  
Illinois Health & Science

Patrick Phelps  
President & CEO  
Sofie Network, Inc.

Enclosure: Resume for Mr. Frank Plastini