



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 Warrenton Road, Suite 210
Lisle, IL 60532-4352

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

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.



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:

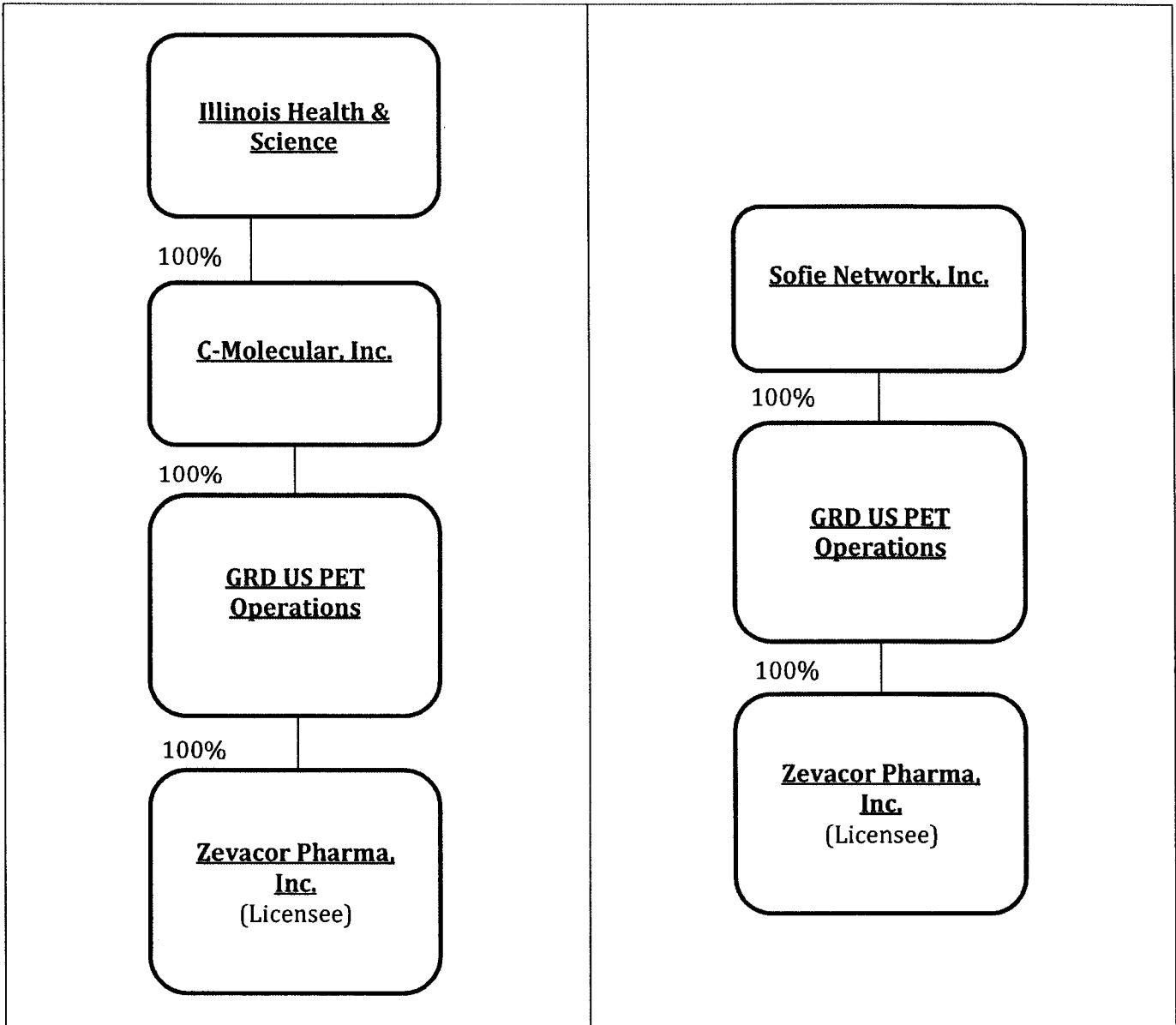
5.1 Description of the Transaction

- 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:



**Current Structure
(As Relevant to NRC Review)**

**Post-Closing Structure
(As Relevant to NRC Review)**



Since the NRC licensee will not change, no administrative, conforming license amendment is necessary to effectuate the planned transaction.



- 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.

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.



- 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



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.



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 (201) 697-0076, Frank Plastini at (518) 357-8645 (office) or (518) 313-2369 (cell), or via email to regulatoryaffairs@zevacor.com with any questions regarding this issue.

Sincerely,

A handwritten signature in black ink that reads "Timothy D. Stone, Jr." with a horizontal line underneath.

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

A handwritten signature in black ink that reads "Patrick Phelps" with a horizontal line underneath.

Patrick Phelps
President & CEO
Sofie Network, Inc.

Enclosure: Resume for Mr. Frank Plastini

518-357-8645 Office
Rexford, New York 12148

518-313-2369 Cell
fplastini@zevacor.com

Frank L. Plastini

Objective

To lead a dynamic, proactive team of Environmental, Health & Safety professionals that can be responsive to our customers needs.

Experience

3/2017-Present Zevacor Pharma Albany, NY

Director Radiation Compliance & EHS/CRSO

- Managed the Radiation Compliance Program for 14 Nuclear Pharmacies, including state RAM Licenses, NYS DEC Effluent Permit. Maintain compliance with OSHA Standards and Company Polices. Additional responsibilities include maintaining our RAM license for our Research and Development facility in Somerset, NJ.
- Develop and present training classes for Hazard Communication, Blood-borne Pathogens, LOTO, Radiation & Chemical Emergency Response and Accident & Incident investigations.
- Provide Auditing of Nuclear Pharmacies to review compliance with ALARA principles, adherence to license conditions and regulations as well as GMP and FDA requirements.
- Updated our Radiation Safety Manual and SOPs.
- Regulatory Interface during State and NRC Radiation inspections.

3/2006-3/2017 Siemens Molecular Imaging Albany, NY

EHS Specialist/RSO

- Managed the EHS Program for 15 Nuclear Pharmacies, including state RAM Licenses, NYS DEC Effluent Permit, DOT Transportation Permits. Maintain compliance with OSHA Standards and Company Polices.
- Develop and present training classes for Hazard Communication, Blood-borne Pathogens, LOTO, Radiation & Chemical Emergency Response and Accident & Incident investigations.
- Provide Auditing of Nuclear Pharmacies to review compliance with ALARA principles, adherence to license conditions and regulations as well as GMP and FDA requirements.
- Provide PM assistance during facility renovations to ensure our facilities maintain compliance with Federal and State Building Codes as well as NFPA and FM guidelines.
- Developed waste program improvements to reduce hazardous waste costs by 70%.

8/2001-3/2006 GE Global Research Center Niskayuna, NY

Radiation Safety Manager/RSO

- Managed the Research Center's Broad Scope RAM License to include ordering of isotopes, compliance with NYS regulations and our broad scope license, maintained our film badge

database, x-ray producing equipment inventory & registration, and RAM survey reports. Radiatic Safety Officer for the facility.

- Developed and assisted with the renovation and building of a new Hot Lab for development of PET imaging agents. Ensure that the new facility complies with the New York State Building Code, and NFPA Life Safety Code.
- Developed and implemented training & compliance programs for Radiation, Chemical & Biological Safety, as well as emergency response team training.
- Provided Regulatory Agency interaction during routine inspections by the DEC, DOL, and DEA. Maintained the facilities DEA, RAM and Asbestos License's.
- Radiation/Chemical Safety Officer for our Emergency Response Team.
- Responsible for the management of three chemical stock rooms including MSDS creation & tracking and chemical inventory.
- Provided industrial hygiene monitoring services for our construction project to support their application to become the first GE sponsored construction project to successfully achieve VPP status.

10/1997-8/2001 Texas Instruments Merrimack, NH

Health & Safety Engineer

- Provided emergency response services, chemical labeling, industrial hygiene monitoring, project management, occupational health & safety program development and implementation, contractor supervision for 4" & 6 " M-Fab semiconductor facility.
- Radiation Safety Officer for our facility to include surveys, badge exchange, training of staff and data analysis.
- Managed a variety of Environmental Remediation Projects, including surveys, preparation of budgets, as well as plans and specifications.
- Assisted with the management of our contract workforce during the design and construction of a new 15,000sf class 100 clean room.
- Coordinated and managed our medical services contractor. Including accident investigations, preparation of paperwork, OSHA log and injury/illness statistics. Additionally, coordination with Human Resources on workers compensation issues and return to work programs.

7/1996-10/1997 ET Environmental Consultants Andover, MA

Project Manager

- Developed a comprehensive Health and Safety Plan for a 16 acre hazardous waste site undergoing remediation. The project included training numerous subcontractors, scheduling waste shipments and maintaining the project budget.
- Provided training for all subcontractors performing work at our various projects.

4/1993- 7/1996 Clean Harbors South Boston, MA

EHS Engineer

- Maintained, coordinated and scheduled all the training, medical surveillance and accident records for the largest field service division of Clean Harbors.
- Served as the incident commander/sso for our emergency response projects.
- Conducted OSHA compliance air sampling, data analysis and report documentation for field work performed at various locations.
- Managed several remediation projects involving decontamination of radiological laboratories involving Tritium, & Cobalt.

11/1990- 4/1993 M/A-COM Burlington, MA

Staff EHS Engineer

- Provided emergency response services, auditing of laboratories, industrial hygiene monitoring, project management, occupational health & safety program development and implementation, contractor supervision for the Burlington Semiconductor Division of M/A-COM.
- Assisted the Facility Manager with training his work force on such topics as Hazcom, Electrical Safety, Chemical Safety & PPE programs to name a few.
- Coordinated accident investigations and workers compensation issues with our Medical and Human Resources Departments.
- Radiation Safety Officer for our Tritium and Cobalt 60 laboratory

6/1988–11/1990 Balsam Environmental Consultants Salem, NH

Field Engineer

- Team Leader for asbestos abatement services.
- Provided design services for renovations and upgrades on exhaust systems.
- Provided training to our in-house staff of engineers and field personnel.

Education M.S., Industrial Hygiene, University of Massachusetts, Amherst, MA
B.S. Biology/Chemistry, State University of New York, Albany, NY

Specialized Training ORAU Radiation Safety Officer Training,
ABSA Biosafety Officer Training,
ATMI Toxic Gas Control Systems Training,
Asbestos Building Inspector, USEPA,
40hr HAZWOPER, OSHA
Albany Medical College, "Handling Laboratory Animals"

References Available upon request

ORIGIN ID:WGOA (703) 787-7900
JAMES YORK
IBA MOLECULAR NORTH AMERICA, INC.
21000 ATLANTIC BLVD SUITE 730

DULLES, VA 20166
UNITED STATES US

SHIP DATE: 19MAY17
ACTWGT: 1.00 LB
CAD: 107800661/NET3850

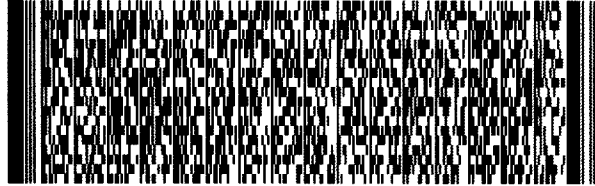
BILL SENDER

TO **MATERIALS LICENSING BRANCH**
U.S. NRC, REGION III
2443 WARRENVILLE ROAD
SUITE 210
LISLE IL 60532

(630) 829-9500
INV.
PO:

REF: NRC RAM TRANSFER PHARMA
DEPT:

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FedEx
Express



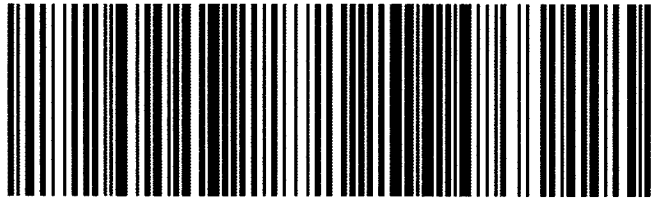
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