SAFETY EVALUATION REPORT
PROPOSED TRANSFER OF CONTROL OF BYPRODUCT MATERIALS LICENSE NUMBER 45-25221-01MD, Zevacor Pharma, Inc.

DATE: August 18, 2017

DOCKET NO.: 030-32974

LICENSE NO.: 45-25221-01MD

LICENSEE: Zevacor Pharma, Inc.
21000 Atlantic Boulevard, Suite 730
Dulles, Virginia 20166

TECHNICAL REVIEWER: Janice Nguyen, Senior Health Physicist, Region I

SUMMARY AND CONCLUSIONS

Zevacor Pharma, Inc. is authorized by NRC License 45-25221-01MD for the possession and use of byproduct material for the purposes of preparation, distribution, and redistribution of radioactive drugs and radiochemicals to authorized recipients for medical use. The U.S. Nuclear Regulatory Commission (NRC) staff reviewed a request for consent to an indirect license transfer submitted by Zevacor Pharma, Inc., a wholly-owned subsidiary of GRD US PET Operations, Inc. (GRD). GRD is a wholly-owned subsidiary of C-Molecular, Inc. (C-Molecular). The indirect transfer will result from a sale between Sofie Network, Inc. (Sofie Network) and C-Molecular, which is wholly owned by Illinois Health & Science. Under the planned transaction, C-Molecular will sell 100% of its shares in GRD to Sofie Network. Following the sale, GRD will be a wholly owned subsidiary of Sofie Network and Zevacor Pharma, Inc. will remain a wholly owned subsidiary of GRD. The indirect transfer of control is described in Agency Documents Access and Management System (ADAMS) package accession number ML17150A307. The ADAMS package consists of the following agency documents: letter dated May 15, 2017 (redacted version) (ML17156A736), letter dated May 15, 2017 (non-redacted version) (ML17150A308), letter dated June 28, 2017 (ML17194A720), letter dated July 17, 2017 (ML17214A209), letter dated July 28, 2017 (ML17219A593), letter dated August 1, 2017 (ML17216A445), and letter dated August 8, 2017 (ML17230A334).

The licensee's request for consent to an indirect transfer of ownership was posted for public comment on the NRC website for 30 days in accordance with 10 CFR Part 2 and following the guidance provided in the NRC's Regulatory Issue Summary 2014-08. No comments were received from members of the public.

The request for consent was reviewed by NRC staff for an indirect transfer of control of a 10 CFR Part 30 license using the guidance in NUREG 1556, Volume 15, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Changes of Control and About Bankruptcy Involving Byproduct, Source, or Special Nuclear Materials Licenses," dated November 2000. The NRC staff finds that the information submitted by Zevacor Pharma, Inc. and Sofie Network sufficiently describes and documents the transaction and commitments made by the both parties.

As required by 10 CFR 30.34 and section 184 of the Atomic Energy Act of 1954, as amended (the Act), NRC staff has reviewed the application and finds that the proposed transfer of control is in accordance with the Act. The staff finds that, after the transfer of control, Zevacor Pharma, Inc. will remain qualified to use byproduct material for the purpose requested, and will continue to have the equipment, facilities, and procedures needed to protect public health and safety, and promote the common defense and security.

SAFETY AND SECURITY REVIEW

According to data obtained from the NRC's Web Based Licensing system, Zevacor Pharma, Inc. has been an NRC licensee since February 4, 1993. The NRC conducted an inspection at the Kansas City, Missouri location on March 26, 2015, and identified one violation for a failure to perform linearity testing on the dose calibrator. The NRC conducted an inspection at the Morgantown, West Virginia location on August 24, 2016, and no violations were identified. The commitments made by Zevacor Pharma, Inc. and Sofie Network state that there will be:

A. no change to the radiation safety officer listed on the NRC licenses;

B. no change in personnel involved in licensed activities;

C. no change in the locations, facilities, and equipment authorized in the NRC license;

D. no change in the radiation safety program authorized in the NRC license; and

E. no change in the organization's name listed in the NRC license.

Further, the licensee will maintain required surveillance records and decommissioning records as required by NRC regulations.

Momentum Biosciences currently holds a radioactive materials license issued by the State of California (No. 7762-19). Momentum Biosciences has partial ownership of Sofie Biosciences, Inc., which is the parent company of Sofie Network. Sofie Biosciences, Inc. also held a radioactive materials license issued by the State of California (No. 7989-19), but this license was terminated on February 5, 2016. For security purposes, Zevacor Pharma, Inc. and Sofie Network, the ultimate parent post-closing, are considered to be known entities following the guidance provided by the NRC's Office of Nuclear Material Safety and Safeguards (NMSS)[1] "Checklist to provide a basis for confidence that radioactive materials will be used as specified on the license," September 3, 2008 revision. The purpose of this checklist is for the NRC to obtain reasonable assurance from new license applicants or NRC licensees transferring control of licensed activities that the licensed material will be used for its intended purpose and not for malevolent use.

Zevacor Pharma, Inc. is required to have decommissioning financial assurance based on the types and amount of material authorized in License No. 45-25221-01MD. The licensee did not indicate that the transfer would have any effect on decommissioning financial assurance and stated that after the transfer, it would continue to accept full responsibility for decommissioning.

REGULATORY FRAMEWORK

Zevacor Pharma, Inc.'s License No. 45-25221-01MD was issued under 10 CFR Part 30, Rules of General Applicability to Domestic Licensing of Byproduct Material. The Commission is required by 10 CFR 30.34 to determine if the transfer of control is in accordance with the provisions of the Act and give its consent in writing.
10 CFR 30.34(b) states: "No license issued or granted pursuant to the regulations in this part and parts 31 through 36, and 39 nor any right under a license shall be transferred, assigned or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person, unless the Commission shall, after securing full information, find that the transfer is in accordance with the provisions of the Act and shall give its consent in writing."

As previously indicated, the staff evaluation is based on guidance in NUREG-1556, Volume 15. Zevacor Pharma, Inc.'s request for consent describes an indirect transfer of control and, as such, the transfer requires NRC consent.

DESCRIPTION OF TRANSACTION

The indirect transfer of control is described in Agency Documents Access and Management System (ADAMS) package accession number ML17150A307. The ADAMS package consists of the following agency documents: letter dated May 15, 2017 (redacted version) (ML17156A736), letter dated May 15, 2017 (non-redacted version) (ML17150A308), letter dated June 28, 2017 (ML17194A720), letter dated July 17, 2017 (ML17214A209), letter dated July 28, 2017 (ML17219A593), letter dated August 1, 2017 (ML17216A445), and letter dated August 8, 2017 (ML17230A334). After completion of the sale, Zevacor Pharma, Inc. will continue as the licensee and remain in control of all licensed activities under Materials License No. 45-25221-01MD. The NRC staff finds that the request for consent adequately provides a complete and clear description of the transaction and is consistent with the guidance provided in Appendix F of NUREG-1556, Volume 15.

TRANSFEREE'S COMMITMENT TO ABIDE BY THE TRANSFEROR'S COMMITMENTS

The NRC staff finds that the information submitted by Zevacor Pharma, Inc. and Sofie Network, Inc. sufficiently describes and documents the commitments made by both parties and is consistent with the guidance in NUREG-1556, Volume 15.

ENVIRONMENTAL REVIEW

An environmental assessment for this action is not required since this action is categorically excluded under 10 CFR 51.22(c)(21).

CONCLUSION

The staff has reviewed the request for consent submitted by the licensee with regard to an indirect transfer of control of byproduct materials license No. 45-25221-01MD and consents to the transfer pursuant to 10 CFR 30.34(b).

Consistent with the guidance in NUREG-1556, Volume 15, the submitted information sufficiently describes the transaction; documents the understanding of the license and commitments of the transferee; demonstrates that personnel have the experience and training to properly implement and maintain the license and that they will maintain the existing records; and provides that, in the future, the transferee will abide by all existing commitments on the license.

Therefore, the staff concludes that the proposed transfer of control would not alter the previous findings, made under 10 CFR Part 30, that licensed operations will not be inimical to the common defense and security, or to the health and safety of the public.