SAFETY EVALUATION REPORT
PROPOSED CHANGE OF CONTROL FOR BYPRODUCT MATERIALS LICENSE NUMBER 06-30726-01, MELINTA THERAPEUTICS, INC.

DATE: April 9, 2014

DOCKET NO.: 030-35971

LICENSE NO.: 06-30726-01

LICENSEE: Melinta Therapeutics, Inc.
300 George Street, Suite 301
New Haven, Connecticut 06511

TECHNICAL REVIEWER: Dennis Lawyer

SUMMARY AND CONCLUSIONS

Rib-X Pharmaceuticals, Inc., doing business as Melinta Therapeutics, Inc., is authorized by NRC License No. 06-30726-01 for the possession and use of byproduct material for purposes of research and development as defined in 10 CFR 30.4. The U.S. Nuclear Regulatory Commission (NRC) staff reviewed a request for consent to an indirect transfer of control submitted by Melinta Therapeutics, Inc. that resulted from an investment into preferred stock. On November 24, 2012, Rib-X Pharmaceuticals, Inc. consummated the first tranche of a preferred stock financing led by Vatera Healthcare Partners LLC ("Vatera") in which Vatera became the majority stock holder and obtained indirect control of the company. Additional purchases of preferred stock were obtained on October 24, 2013, November 19, 2013, and January 23, 2014. After the last purchase of preferred stock, Vatera owns approximately 75% of the company stock (on an as-converted basis). Prior to the November 2012, financing, affiliates of Warburg Pincus controlled the Company at the Board and stockholder level, owning approximately 72% of the Company's then outstanding shares (on an as-converted basis). The indirect transfer of control is described in Agencywide Documents Access and Management System (ADAMS) Accession Number ML14027A252 and ML14084A160. By letter dated October 24, 2013, Rib-X Pharmaceuticals, Inc. requested that its name be changed to Melinta Therapeutics, Inc. (ADAMS Accession No. ML13323B455). This was a change in name only and not a change in control.

The NRC staff reviewed the request for an indirect change in control of a 10 CFR Part 30 license using the guidance in NUREG-1556, Volume 15, "Consolidated Guidance About Materials Licenses - 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 Melinta Therapeutics, Inc. sufficiently describes and documents the transaction and commitments made by Vatera and Melinta Therapeutics, Inc.

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 change in control is in accordance with the Act. The staff finds that, after the change of control, Melinta Therapeutics, 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 security of licensed material.

SAFETY AND SECURITY REVIEW

According to data obtained from the NRC's Web-Based Licensing Database (WBL), Melinta Therapeutics, Inc. has been an NRC licensee since May 16, 2002. The NRC conducted a main office inspection of Rib-X Pharmaceuticals, Inc. on April 1, 2013, and no violations or safety concerns were identified during this inspection. The commitments made by Vatera and Melinta Therapeutics, Inc. state that Melinta Therapeutics, Inc. (License No. 06-30726-01):

A. will not change the radiation safety officer listed in the NRC license;

B. will not change the personnel involved in licensed activities;

C. will not change the locations, facilities, and equipment authorized in the NRC license;

D. will not change the radiation safety program authorized in the NRC license;

E. will not change the organization's name listed in the NRC license; and

F. will keep regulatory required surveillance records and decommissioning records.

Since Vatera did not have direct or indirect control of a NRC or Agreement State material license before November 24, 2012, a pre-licensing visit was conducted at the Melinta Therapeutics, Inc. facility on January 9, 2014. For security purposes, Vatera was reviewed following the guidance provided by the NRC's Office of Federal and State Materials and Environmental Management Programs (FSME) "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.

Melinta Therapeutics, Inc. is not required to have decommissioning financial assurance based on the types and amount of radioactive material authorized by License No. 06-30726-01.

REGULATORY FRAMEWORK

Melinta Therapeutics, Inc.'s License No. 06-30726-01 was issued under 10 CFR Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material." The NRC is required by 10 CFR 30.34 to determine if the change 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. As discussed in NUREG-1556, Volume 15, the NRC is generally using the term "change of control" rather than the statutory term "transfer" to describe the variety of events that could require prior notification and written consent of the NRC. The central issue is whether the authority over the license has changed. Melinta Therapeutics, Inc.'s request for consent describes an indirect change of control resulting from a planned investment by Vatera in which Vatera currently is the majority shareholder of the Company's outstanding shares and has the right to designate 4 out of 7 of the Board member of the licensee, as such, the transfer requires NRC consent.

DESCRIPTION OF TRANSACTION

The transaction is described in ADAMS Accession Number ML14027A252 and ML14084A160. After completion of the investment, Rib-X Pharmaceuticals, Inc. continued as the licensee but was controlled by Vatera under Byproduct Materials License No. 06-30726-01. On October 7, 2013, Rib-X Pharmaceuticals, Inc. changed their name to Melinta Therapeutics, Inc. 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 Melinta Therapeutics, Inc. sufficiently describes and documents the commitments made by Vatera and Melinta Therapeutics, Inc., and is consistent with the guidance in NUREG-1556, Volume 15. Vatera and Melinta have agreed to abide by the NRC license and regulations.

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 both parties with regard to an indirect change of control of Byproduct Materials License No. 06-30726-01 and approves the application pursuant to 10 CFR 30.34(b).

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

Therefore, the staff concludes that the proposed change in 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.