UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
2100 RENAISSANCE BOULEVARD, SUITE 100
KING OF PRUSSIA, PENNSYLVANIA 19406-2713

January 30, 2014

Docket No. 03035971 License No. 06-30726-01
Control No. 582442

Erin Duffy, Ph.D.
Chief Scientific Officer
Melinta Therapeutics, Inc.
300 George Street, Suite 301
New Haven, CT 06511

SUBJECT: MELINTA THERAPEUTICS, INC., REQUEST FOR ADDITIONAL INFORMATION CONCERNING APPLICATION FOR AMENDMENT TO LICENSE, CONTROL NO. 582442

Dear Dr. Duffy:

This is in reference to your letters to the U.S. Nuclear Regulatory Commission (NRC) dated October 24, 2013, and January 20, 2014, notifying the NRC of a transfer of control of NRC Materials License No. 06-30726-01. Under Section 30.34(b) of Title 10 of the Code of Federal Regulations (10 CFR), no license may be either "directly or indirectly, through transfer of control . . . 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." In order for the NRC staff to continue its review of the corporate transaction, the following additional information should be provided:

1. The January 20, 2014, letter contains a statement in Item 8, that "Vatera has acknowledged and agreed that, through its control of the Board of Directors, it oversees such policies and procedures and regularly reviews and monitors the Company's compliance related thereto." The letter is signed by an officer of Melinta Therapeutics, Inc. (Melinta). Items 2 and 9 also refer to information concerning Vatera Healthcare Partners LLC (Vatera). Please provide a letter written on Vatera's letterhead and signed by a senior official of the company that the October 24, 2013, and January 20, 2014, letters have been read and that Vatera officials are in agreement with the content of the above letters, and that Vatera will abide by all constraints, license conditions, requirements, representations, and commitments identified in and attributed to the existing license.

2. The description of the transaction and the pre- and post-corporate structure and controlling interests needs to be more explicit. Please ensure that your response addresses the following:

    a. The January 20, 2014, letter states that prior to November 15, 2012, Warburg Pincus owned 72 percent of the outstanding stock of Rib-X. Please describe the corporate structure of Rib-X Pharmaceuticals, Inc. prior to November 15, 2012,

showing any other stock or share owners.

b. The October 24, 2013, letter indicates that Rib-X is changing its name to Melinta Therapeutics, Inc. A review of the corporation status records in Connecticut and Delaware appears to indicate that Melinta was a pre-existing company prior to October 24, 2013. Please indicate the corporate formation date of Melinta as a legal entity in Connecticut and Delaware and provide documentation supporting the Rib-X name change. In addition, please provide a description of the corporate structure of Melinta before and after October 24, 2013, showing any owners, affiliates, or parent companies.

c. The information provided in the January 20, 2014, letter references a first and second tranche of preferred stock financing. Describe the corporate structures of Melinta and Rib-X Pharmaceuticals, Inc. after the first tranche that closed on November 15, 2012. In addition, provide a description of changes in corporate structures, stock ownership, or parent companies that occurred as a result of the second tranche, and any other subsequent corporate transactions pertaining to the direct or indirect control of Rib-X through the date of this letter. Also, describe the current division of stock ownership and control of the Board of the NRC licensee.

3. As stated in 2.b., it appears that Melinta was a viable company prior to the first tranche. Indicate whether Rib-X was merged into Melinta during the first or second tranche or whether Melinta was dissolved with Rib-X taking the name.

Current NRC regulations and guidance are included on Materials Licensees Toolkit Index located on NRC's website at http://www.nrc.gov/materials/miau/materials licensee toolkit index.html; select **Research and Development.** For guidance specific to transfer of controls, please see NUREG-1556, Volume 15, "Consolidated Guidance About Material Licenses – Program-Specific Guidance About Changes of Control and Bankruptcy Involving Byproduct, Source, or Special Nuclear Material Licenses," which may also be found on the NRC's website at http://pbadupws.nrc.gov/docs/ML003778305.pdf. You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-866-512-1800. The GPO is open from 8:00 a.m. to 5:30 p.m. EST, Monday through Friday (except Federal holidays).

In accordance with 10 CFR 2.390 of the NRC's "Agency's Rules of Practice and Procedure," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the Publically Available Records component of the NRC's Agencywide Document Access and Management System (ADAMS). ADAMS is accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html.

Please provide the requested information within 30 calendar days from the date of this letter. The NRC staff will continue its review upon receipt of this information. Please reply to the attention of Dennis Lawyer at the Region I Office and refer to Mail Control No. 582442. If you have any technical questions regarding this deficiency letter, please call me at (610) 337-5075 or Dennis Lawyer at (610) 337-5366.

Thank you for your cooperation in this matter.

Sincerely,

Original signed by Steve Courtemanche

Steven Courtemanche
Health Physicist
Commercial, Industrial, R&D and Academic Branch
Division of Nuclear Materials Safety

cc:
Joseph A. Ippolito, Ph.D., Radiation Safety Officer
Sean Ewen, Esq., Legal Counsel Melinta Therapeutics, Inc.
Anna Kim, General Counsel Vatera Holdings. LLC

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