

From: [Lawyer, Dennis](#)
To: [Erin Duffy \(eduffy@melinta.com\)](mailto:Erin.Duffy@melinta.com)
Cc: [Joe Ippolito](#)
Subject: Melinta Therapeutics Inc., Request for Additional Information Concerning Application for a License Amendment, Control 582442
Date: Wednesday, December 11, 2013 3:39:00 PM

Dear Dr. Erin Duffy,

This is in reference to your letter dated October 24, 2013, requesting for amendment to Nuclear Regulatory Commission License No. 06-30726-01, Docket No. 030-35971. In order to continue our review, we need the following additional information:

10 CFR 30.34(b) states that “no license issued or granted pursuant to the regulations...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...find that the transfer is in accordance with the provisions of the Act and shall give its consent in writing. Although not specifically addressed by 10 CFR 30.34, licensees undergoing a name change may also be affected by this regulation.

Control over licensed activities can be construed as the authority to decide when and how a license (licensed material and/or activities) will be used. A change of ownership may be an example of a change of control. The central issue is whether the authority over the license has changed. In all cases, determining whether a change of control has taken place or whether a change is in name only is the Commission’s responsibility.

Licensees must notify the Commission when they are undergoing a possible change of control and/or a change of name. While this notification is not required within a certain time frame, NRC needs adequate time to review the submittal to ensure that the transfer is in accordance with the regulations.

Definitions: Transferee: A transferee is an entity that proposes to purchase or otherwise gain control of an NRC-licensed operation.

Transferor: A transferor is an NRC licensee selling or otherwise giving up control of a licensed operation.

In the letter dated October 24, 2003, you have already stated that there were no changes in personnel or management representative. In a telephone conversation on December 11, 2013, you discussed that there had been changes to the investors such that Vatera Healthcare Partners was a major investor. This appears to be an indirect change of control.

As stated in NUREG-1556, Volume 15, “Consolidated Guidance About Material Licenses, “Program-Specific Guidance About Changes of Control and About Bankruptcy Involving Byproduct Source, or Special Nuclear Material Licenses,” Section 5, please provide:

1. A description of transaction that results in a change in indirect control. Please include the public release statement associated with the November 17, 2012, change. Please describe the current ownership of the company and what the

ownership was before the change in November 2012.

2. Describe changes in the organization that exercises control over the licensed program.
3. Describe changes in place of use, including potentially affected adjacent areas, as required.
4. Describe changes in facilities where licensed material is to be used or stored.
5. Describe changes in equipment to be used in the licensed program.
6. Submit relevant procedural changes.
7. State that you have maintained your decommissioning and related records.
8. Please provide an agreement by the transferee to abide by all constraints, license conditions, requirements, representations, and commitments identified in and attributed to the existing license or a description of the transferees' program to ensure compliance with the license and regulations.

We will continue our review upon receipt of this information. Please reply to my attention at the Region 1 Office and refer to Mail Control No. 582442. If you have technical questions regarding this letter, please call me at (610) 337-5366.

The NRC's Safety Culture Policy Statement became effective in June 2011. While a policy statement and not a regulation, it sets forth the agency's *expectations* for individuals and organizations to establish and maintain a positive safety culture. You can access the policy statement and supporting material that may benefit your organization on NRC's safety culture Web site at <http://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html>. We strongly encourage you to review this material and adapt it to your particular needs in order to develop and maintain a positive safety culture as you engage in NRC-regulated activities.

Please note that you may not reply to this letter by return e-mail. Your reply must be in writing by letter or facsimile (610-337-5269). If we do not receive a reply from you within 30 calendar days from the date of this e-mail, we will assume that you do not wish to pursue your application.

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