



Region I Office
Division of Nuclear Materials Safety
2100 Renaissance Boulevard
Suite 100
King of Prussia, PA 19406-2713
(610)337-5000

Telephone Conversation Record

Date: January 28, 2014

License No.: 06-30726-01

Docket No. *(no hyphens)*: 03035971

Mail Control No.: 582442

Licensee Name: Melinta Therapeutics, Inc.

Participant(s) Name/Title: Joseph A. Ippolito, Ph.D./Radiation Safety Officer
Anna Kim, General Counsel (Vatera Holdings, LLC)

Work Telephone No.: 203-848-6274

Business Cellphone No.: N/A

NRC Representative Name/Title: Steven R. Courtemanche/Health Physicist

Subject: Request for Additional Information

(This is the title that will be used in ADAMS)

Discussion: (08:30) I left a message on Mr. Ippolito's voice-mail. (08:35) Dr. Ippolito returned my call. I explained that a member of the NRC Office of the General Counsel (OGC) had reviewed the documents submitted to the NRC in support of the amendment and came to the conclusion that more information was necessary. OGC had also remarked that an officer of licensee could not make commitments on behalf of Vatera Healthcare Partners LLC (Vatera) because Vatera was the parent company of Melinta. Information would be required of the corporate organization showing Melinta's position prior to the first tranche in November 2012 and after the second tranche in 2013. Was Rib-X merged into the existing company Melinta? Provide a breakdown of the preferred stock owners prior to the first tranche, after the first tranche, and after the second tranche. I received information on update phone numbers and e-mail addresses for licensee contacts. Dr. Ippolito stated that he would return my call when he obtained the name and position of an individual from Vatera. I stated that I would supply a copy of the letter once it was vetted by OGC. (14:20) Dr. Ippolito called and stated their legal counsel would also like a copy of the document. The contact for Vatera was Anna Kim but he did not have a title for her. I stated that I would contact her for the information. (15:00) I spoke with Ms. Kim. I explained to her why I needed the signature of a corporate official at Vatera Healthcare Partners, LLC. She stated that the document could be sent to her and she would see to it that it was signed by the proper official.

Action Required: Issue RAI

SUNSI REVIEW

Document Availability: ☒ Public or ☐ Non-Public

Document Sensitivity:

(select "1" value to the right)

<input checked="" type="checkbox"/>	Non-Sensitive	<input type="checkbox"/>	MD 3.4 Non-Public B.1 (Non-Sensitive)
<input type="checkbox"/>	Non-Sensitive Copyright	<input type="checkbox"/>	MD 3.4 Non-Public A.3 (Sensitive Security Related
<input type="checkbox"/>	Sensitive – Proprietary	<input type="checkbox"/>	MD 3.4 Non-Public A.4 (Sensitive Proprietary
<input type="checkbox"/>	Sensitive – Privacy Act (includes Personally Identifiable Information (PII))	<input type="checkbox"/>	MD 3.4 Non-Public A.5 (Sensitive-Privacy Act)
<input type="checkbox"/>	Sensitive – Internal, Periodic Review required (All Other Sensitive Internal Info.)	<input type="checkbox"/>	MD 3.4 Non-Public A.6 (Sensitive-Federal, State, etc)
<input type="checkbox"/>	Sensitive – Security-Related-Periodic Review Required	<input type="checkbox"/>	MD 3.4 Non-Public A.7 (Internal)

SUNSI Review Completed by: Steven R. Courtemanche