Prelude THERAPEUTICS

STAR Campus II
550 S. College Avenue, Suite 110
Newark, DE 19713

January 11, 2017

03-35398-01
03039018

Mr. Dennis Lawyer
Health Physicist
U.S. Nuclear Regulatory Commission, Region 1
2100 Renaissance Blvd # 100
King of Prussia, PA 19406

Subject: Prelude Therapeutics
R&D Materials License Application
Mail Control No. 592649

Dear Mr. Lawyer:

In response to your e-mail dated January 4, 2017 and addressed to Mr. Min Wang (Prelude) and Ms. Jessica Leonard (IES Engineers) we provide the following requested information:

1) NUREG-1556 Vol. 7, Revision 1 Section 8.8 states that the applicant should provide "A description of the radiation safety training program, including topics covered, groups of workers, assessment of training, qualifications of instructors, and the method and frequency of training." In Item 8 of your application you discuss "Training for Individuals Working in or Frequenting Restricted Areas." you included the topics covered, groups of workers who will receive the training, qualifications of the instructor and the method and frequency of the training, however you did not include how the training will be assessed. Please provide additional information as to how the training provided to these individuals will be assessed.

Prelude Response: Verification of employee comprehension (assessment of training) will be performed utilizing a written exam that focuses on key concepts covered during training. Employees must earn a passing grade to complete the training course and be permitted to work with RAM.

2) NUREG-1556 Vol. 7, Revision 1 Section 8.10.3 states that "With regard to unsealed material, licensees use various methods to account for receipt, use, transfer, disposal, and radioactive decay. In Item 10 of your application, Section C.2. discusses "Radioactive Material Inventory." You state that RAM use and Decay in Storage records will be separate from this inventory. It is unclear how the total amount of material on hand at any given time will be known if these two items are kept

separate. Please confirm that a tracking method will be in place that accounts for all material onsite in order to ensure that possession limits are not exceeded.

Prelude Response: At this point the site plans to log the receipt of RAM into an excel workbook where they will also track storage for disposal and ultimate disposal. This excel workbook will be the "Inventory." Separate Radioactive Material Use Logs will be maintained in the laboratory to track the use of RAM from a particular vial and/or shipment. Once the vial is empty, the Radioactive Material Use Log will be returned to the RSO for review and update of the inventory as necessary. The Decay in Storage record is an independent form on which the particular requirements for decay in storage are logged. However, as noted below, this form will not be utilized at this time as the site has only requested licensing of 3H, a long half-life isotope.

3) NUREG-1556 Vol. 7, Revision 1 Section 8.10.4 discusses Occupational Dose. Your application does not address occupational dose. Please confirm that either 1) You have done a prospective evaluation and determined that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10 percent of the allowable limits in 10 CFR Part 20 or 2) That you will monitor individuals in accordance with the criteria in Section 8.10.4 entitled "Radiation Safety Program – Occupational Dose in NUREG-1556 Vol. 7, Revision 1, "Consolidated Guidance about Materials Licenses: Program Specific Guidance about Academic, Research and Development, and Other Licenses of Limited Scope.

Prelude Response: A prospective evaluation has determined that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10 percent of the allowable limits in 10 CFR Part 20. Evaluation: (1) External dose is not expected due to the limited range of H-3 beta particles, (2) Using Regulatory Guide 8.25 guidance, internal dose is not expected to be significant. The ALI for H-3 is 80mCi. The maximum amount of H-3 used annually by an individual will be 2-3 mCi which is less than 1x the ALI, well below the level at which monitoring is recommended by the Regulatory Guide 8.25 (10,000x the ALI).

4) Please note that although your application states in Item 11 that "Prelude may perform waste Decay in Storage on-site," the license issued to you will not authorize Prelude to perform Decay in Storage since the requested isotope has a half-life greater than 120 days. No response is required for this item.

Prelude Response: Agreed.

5) NUREG-1556 Vol.7, Revision 1 Section.7.2 discusses Authorized Users. In your application you did not list any Authorized Users for the material requested. Please submit a list of Authorized Users and provide information demonstrating that each Authorized User is qualified by training and experience to use the requested license material.

Prelude Response: At this time there are no Authorized Users beyond the RSO.

6) In Item 6 "Purposes for Which Licensed Material Will be Used" and Item 8 "Training for Individuals Working in or Frequenting Restricted Areas" you reference the "Pennsylvania Code (PA Code)." Since

you are applying for a license in Delaware under the NRC's jurisdiction, please confirm that you will follow NRC regulations in Title 10 of the Code of Federal Regulations.

Prelude Response: Agreed. Prelude is aware of the applicable regulations located in 10 CFR.

Thank you for your prompt response to our submission. Should you require further information, please feel free to contact Mr. Wang or Ms. Leonard.

Sincerely,

Kris Vaddi, DVM, Ph.D.
CEO & Founder

cc: M. Wang, Prelude
J. Leonard, IES