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Subject: PRELUDE THERAPEUTICS INCORPORATED, REQUEST FOR ADDITIONAL INFORMATION CONCERNING NEW LICENSE APPLICATION FOR RESEARCH AND DEVELOPMENT, CONTROL NO. 592649
Date: Wednesday, January 04, 2017 3:08:00 PM

Docket No. 03039018
License No. 07-35398-01
Control No. 592649

Min Wang, Ph.D.
Prelude Therapeutics Incorporated
550 S. College Avenue, Suite 110
Newark, DE 19713

SUBJECT: PRELUDE THERAPEUTICS, REQUEST FOR ADDITIONAL INFORMATION CONCERNING NEW LICENSE APPLICATION FOR RESEARCH AND DEVELOPMENT, CONTROL NO. 592649

Dear Dr. Wang:

Please reply to this email to confirm receipt.

This is in reference to your application dated December 23, 2016, requesting a Nuclear Regulatory Commission license to perform research and development activities. In order to continue our review we need the following additional 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.
- 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.
- 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.

- 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.
- 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.
- 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.

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Med, Ind, & Academic Uses**; then **Licensee Toolkits, see our toolkit index page**. 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).

We will continue our review upon receipt of this information. Please reply to my attention at the Region I Office and refer to Mail Control No. 592649. If you have any technical questions regarding this deficiency letter, please call me at (610) 337-5366.

In order to continue prompt review of your application, we request that you submit your response to this letter by February 4, 2017.

Thank you for your cooperation.

Dennis Lawyer
U.S. NRC Region 1
Health Physicist
610-337-5366