

Prelude
THERAPEUTICS

200 Power Mill Road
Experimental Station E400/3213
Wilmington, DE 19803

Br. 2

FEDERAL EXPRESS

December 1, 2017

Licensing Assistance Section
Nuclear Materials Safety Branch
U.S. Nuclear Regulatory Commission, Region I
2100 Renaissance Boulevard, Suite 100
King of Prussia, PA 19406-2713

Subject: **Final Status Survey Report for the Prelude Newark Facility
License Amendment Request (02)**
License No. 0735398-01
Prelude Therapeutics Incorporated
Newark, Delaware

03039018

To Whom It May Concern:

Enclosed please find the Final Status Survey Report for the Prelude Therapeutics Incorporated (Prelude) facility in Newark, Delaware. Prelude is moving to a new facility at Experimental Station (E400-3213, 200 Powder Mill Rd., Wilmington, DE, 19803). This address was added to the Prelude license via amendment on October 30, 2017. Prelude has decommissioned the 550 South College Avenue facility in accordance with NRC guidance and hereby requests that the NRC release Suite 100 for unrestricted use and remove it from Prelude License No. 0735398-01.

Should you have any questions regarding this amendment or if there is anything we can do to speed this process (to avoid us paying two leases for any longer than we must), please contact our consultant Ms. Jessica Leonard of IES Engineers at jleonard@iesengineers.com or me.

Thank you in advance for assistance with this amendment.

Sincerely,

Kris Vaddi, DVM, Ph.D.
Chief Executive Officer
Prelude Therapeutics Incorporated
Email: kv@preludetx.cm

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

REC RG 1 12 04 17 PM 09 59

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INMSS/RGN1 MATERIALS-002



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**RADIOLOGICAL DECOMMISSIONING
FINAL STATUS SURVEY REPORT**

**PREPARED FOR:
PRELUDE THERAPEUTICS**

IES PROJECT NO. HS171232.02

December 20, 2017

This report submitted by:

Jessica B. Leonard /e/

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Engineer

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Principal - Director, BioPharma/EHS Services



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Attachment C	NRC Form 314 – Certificate of Disposition of Materials



1.0 BACKGROUND INFORMATION

Prelude Therapeutics (Prelude) is a private biotechnology company with a focus on the discovery and development of new medicines targeting the chromatin function to treat cancer and rare diseases. Prelude performed bench-scale research and development, including the use of radioisotopes, in a leased facility at 550 South College Avenue, Newark, Delaware.

Prelude is moving to a new facility at Experimental Station. An amendment to License 07-35390-01 to add the new facility address (Experimental Station E400-3244, 200 Powder Mill Rd., Wilmington, DE, 19803) was approved by the US Nuclear Regulatory Commission (NRC) on October 30, 2017. As a result, Prelude has decommissioned the existing site and prepared this Final Status Survey Report (FSSR) with the intent of releasing its leased space for unrestricted use.

Research activities on site included chemistry, biology, and support administration. All operations were conducted in the leased facility at 550 South College Avenue. Materials used in the research operations included bench-scale amounts of hazardous chemicals, bloodborne pathogens, and tritium. Tritium was used in accordance with the site's NRC Materials License No. 07-35390-01 and the applicable portions of the *Code of Federal Regulations* (CFR).

Prelude retained IES Engineers (IES) to oversee the radiological decommissioning and decontamination of the Newark facility and to prepare all required documentation. As of the date of this report, the radiological lab has been fully decommissioned.

The purpose of this report is to summarize the methods and results of the Final Status Survey and to demonstrate compliance with NRC regulations pertaining to the Decommissioning of a Research and Development facility with a current Radioactive Materials License as well as to demonstrate that the Prelude-occupied portion (Suite 100) of the 550 South College Avenue facility can be released for unrestricted use and is thereby acceptable for sublease.

2.0 SITE INFORMATION

2.1 Site History and Description

The Prelude facility is a portion of a multi-tenant structure located at 550 South College Avenue in Newark, Delaware. At the Prelude address, the facility is single story. The facility consists of modern labs with durable, easily cleaned floors and work surfaces, and proper ventilation. The standard assortment of incubators, centrifuges, and freezers used in a modern laboratory were available. Prelude limited the use of radioactive materials to licensed areas as designated in Attachment C of the Prelude license application.

The facility required key card access to enter and guests were escorted, making it easy to limit accessibility. Licensed material was received, used, and stored only within approved areas. In addition, although licensed materials were secure through the above facility access requirements, stored licensed material was secured by additional means (in a lock box) when authorized personnel were not present.

Prelude Therapeutics (Prelude) is a startup company focused on developing new drugs for cancer targeting novel mechanisms. Radioactive materials (^3H) were used for research and development as defined in Section 30.4 of 10 CFR Part 301, and in accordance with the amounts, forms, and purposes described in the Prelude license application and on the License No. 07-35390-01. There was no animal or human use.

The Radiation Safety Officer (RSO) was Dr. Min Wang. Dr. Wang with assistance from Ms. Jessica Leonard of IES, managed the decommissioning records, including the results of the radiological wipe surveys. All program files are maintained by Dr. Wang.

The Radioactive Material (RAM) use lab was a standard single module lab, modern, with durable, easily cleaned work surfaces, tiled floors, and proper ventilation. It was fully equipped with the standard assortment of equipment, including incubators, refrigerators, freezers, centrifuges, and computers as well as RAM-specific equipment, such as a MicroBeta counter.

Building design features included:

- Dedicated air handling units (AHUs) serving the laboratories
- Laboratory airflow negative (-) to corridors
- Keycard access to the facility
- Impervious counter tops and benches
- Impervious floor covering and coatings

There were no spills or contamination events at the Prelude site that resulted in fixed contamination or where there was reason to believe that contaminants may have spread to inaccessible areas. Records of the cost estimate for the decommissioning funding plan or of the amount certified for decommissioning were not required for this facility or license.

2.2 Site Conditions at Time of Final Survey

Principal Activities ceased on November 20, 2017. Radiological decommissioning began before the cessation of all activities and continued through the week of November 20, 2017. At the time of the Final Status Survey, the RAM laboratory was emptied of all equipment except for equipment requiring a radiological survey to be cleared before shipment.

The Prelude Radiation program was small in scale and users limited to the RSO alone. Prelude was governed by and followed its NRC Radioactive Materials License. IES helped Prelude establish its radiation safety program and train affected employees. There were no indications of misuse of RAM, nor of improper management of the RAM use on site.

Interviews with the RSO provided information as to which equipment had been used with RAM and allowed verification of exactly where RAM had been used for the duration of the license. (RAM was delivered via FedEx directly to the RAM use lab where it was surveyed by the RSO



and stored in a lockbox within a lockable freezer. RAM waste was stored in a locked cabinet within the RAM use lab.)

Due to the small scale of the Prelude program and the short time in which Prelude had RAM on site, characterization surveys were not necessary. Surveys were conducted throughout the RAM lab, along the path where RAM deliveries were transported and in one or two areas where RAM could have been inadvertently spread (the restroom). As expected, no contamination was found during the decommissioning process or final status surveys. Hence, all areas, including RAM use areas, are below the conservative in-house action level of 200 dpm/100 cm² for removable contamination.

2.3 Identity of Potential Contaminants and Release Guidelines

Prelude was licensed to use only ³H. As is common in R&D facilities, RAM was ordered in millicurie or microcurie amounts and used in microcurie amounts. RAM was actively used at the 550 South College Avenue address from February 16, 2017 to November 21, 2017.

Based on these potential contaminants, NUREG 1757, and on the look-up table printed in 63 FR 64132 on November 18, 1998 "Acceptable License Termination Screening Values of Common Radionuclides for Building Surface Contamination," Table 1 shows the acceptable surface contamination guideline values chosen for the site:

Table 2.1: Acceptable Surface Contamination Levels

Isotope	dpm/100cm²	Prelude Limit dpm/ 100 cm²
³ H	1.2 x 10 ⁸	200

To show more than due diligence, Prelude chose to use a site-wide removable contamination limit of 200 dpm/100 cm². All reachable areas, including lab benches, floors, sinks, etc., were surveyed by Prelude and confirmed to be 200 dpm/100 cm² or less. No contamination was found during the surveys; hence, no decontamination was required.

3.0 FINAL STATUS SURVEY OVERVIEW

3.1 Survey Objectives

The purpose of the Final Status Survey is to demonstrate that the on-site radiological conditions satisfy the NRC release guidelines and that the facility can be released for unrestricted use. Prelude and IES particularly strove to show that significant efforts were made to exceed the decommissioning guidelines set forth by the NRC.

3.2 Organization and Responsibilities

After the site assessment and a review of monthly survey locations, Ms. Leonard determined the locations to be covered in the Preliminary/Final Status Surveys. The locations identified



included, but were not limited to, the RAM use and storage lab, the lab corridor, adjacent lab entrances, bathrooms, and the rear entrance. Since only tritium was used on site, only wipe surveys were taken.

3.3 Instrumentation

A MicroBeta 2 Microplate Counter by Perkin Elmer (Serial Number: DG05129231) was used for the analysis of the lab wipes.

3.4 Survey Procedures

Final Survey procedures were based on an evaluation of Prelude's Radioactive Materials License, Prelude's site radiation safety and general safety procedures, NRC regulations, and guidelines for the release of facilities, specifically NUREG 1757.

All areas designated for radioactive use or storage were considered restricted areas and surveyed appropriately. Wipe surveys were completed in all RAM use areas. Wipe surveys were also completed in secondary areas. (See below for definitions of area classifications.) The background wipe was a clean swab inserted into a clean vial and filled with the same type and amount of cocktail as the rest of the samples. Each wipe was analyzed in the same tray at the same time as the other samples from that area. The MicroBeta was set to detect and measure ^3H , ^{14}C , and ^{32}P in counts per minute (cpm) and disintegrations per minute (dpm). Copies of the MicroBeta printouts can be found in Attachments A and B.

3.4.1 Area Classifications

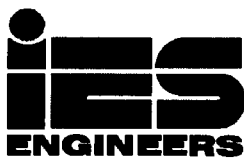
To establish the sample and measurement frequencies, Prelude divided the site into two general area types: Primary and Secondary. The basis for these classifications is listed below:

Primary (Use) Areas

Primary areas are areas that had significant potential for radioactive contamination (based on the facility's operating history). These include areas where radioactive materials were used and stored. There were no records of spills or other unusual occurrences outside of these primary areas that required the inclusion of additional primary areas. Primary areas at Prelude included the Biology Lab, the back door, and the corridor in between. (See Attachment A for a map of these Primary areas.) No areas of contamination were found during the surveys that required decontamination and resurveying.

Primary area final surveys included a higher density of wipes with approximately 30 wipes in the Biology lab. Previous monthly wipe results and input from the RSO were utilized to help determine the locations for the final wipes.

Wipe maps were drawn to include areas of potential contamination, commonly touched items, and in general to take samples in a grid like fashion to ensure all areas received some wipes. Wipe locations included doorknobs and doors, floors, the sink and drain, bench tops, etc. No contamination was found.



Results of the Primary Area surveys are presented in Attachment A. A summary of the results is presented in Section 5.0 Summary.

Secondary (Adjacent & Non-Restricted) Areas

In this facility, all non-primary areas were considered secondary areas. These included areas immediately surrounding or adjacent to locations where radioactive materials were used or stored, areas where RAM deliveries occurred, areas through which RAM was transported, as well as areas further from RAM use, such as the bathrooms, where RAM users could have inadvertently spread contamination.

Since no areas of radiation use existed in these areas, wipe maps for these areas were roughly grid-based to ensure an even and representative numbers of wipes were taken.

Due to the low levels radiation experienced in the primary areas and because tritium was the only isotope in use, direct exposure rate measurements were not taken in these secondary areas.

The results of the Secondary Area surveys are presented in Attachment B. The survey summary is presented in Section 5.0 Summary.

3.5 Data Interpretation

Wipe data was printed in units of cpm and dpm/100cm² (surface activity) as seen in the MicroBeta printouts in Attachments A and B. Dpm values were calculated for ³H because it has the longest half-life of the regularly used isotopes and was the last isotope used or stored. All other isotopes would have decayed to background by the time of the final survey.

3.6 Records

All survey records are maintained by Prelude with the radiation safety program records.

4.0 RADIOACTIVE INVENTORY AND WASTE RECORDS

RSO Dr. Min Wang reviewed the Prelude radioisotope inventory, including the waste inventory, to ensure that all materials received during the life of the license were suitably accounted for and to ensure that remaining materials were appropriately disposed or transported via a licensed vendor to the new facility. No discrepancies were found. Waste manifests from all waste shipments are maintained by the Dr. Wang. Prelude had a total of three waste pickups from Veolia: the first 0.47 mCi of ³H on March 24, 2017, the second 1.68 mCi of ³H on June 5, 2017, and the third and final of 3.04 mCi of ³H on November 22, 2017.

5.0 SUMMARY

The Final Status Survey of the leased Prelude facility in Newark, Delaware, was completed the week of November 20, 2017. As of the date of this report, all RAM on site has been appropriately disposed or transferred to the new site.



Results of the Final Status Surveys demonstrate that all areas surveyed contain no residual activity above the NRC limits for release. No fixed contamination was found, and all areas, including areas of regular RAM use, were below 200 dpm/100 cm² (removable). Hence, the building easily meets the 10 CFR 20.1402, "Radiological Criteria for Unrestricted Use" of 25 mRem/yr.

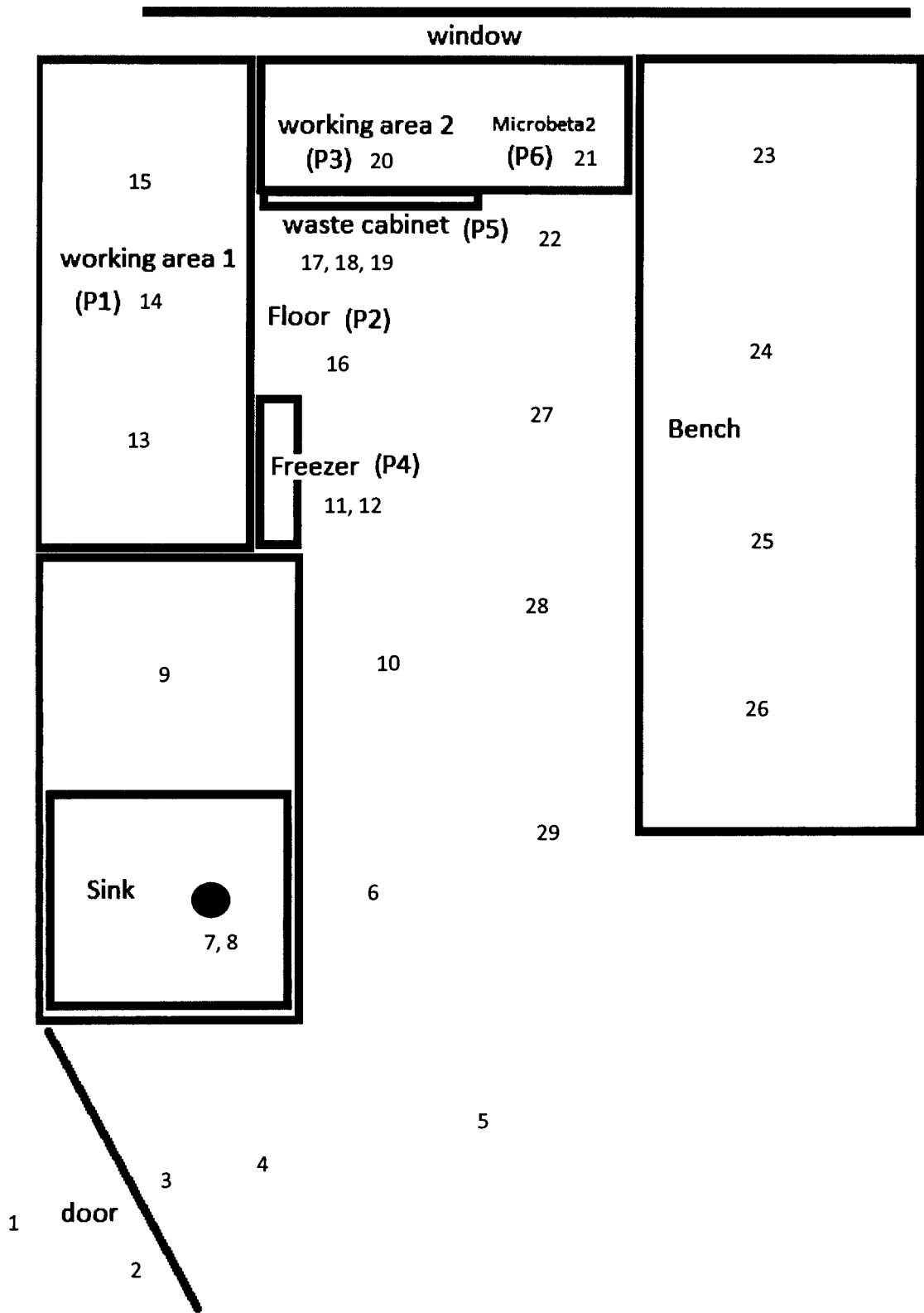
Based on these results and the completion of Form NRC 314, Certificate of Disposition of Materials (see Attachment C), Prelude's leased facility has been decommissioned meeting the requirements of NUREG 1757 "*Consolidated NMSS Decommissioning Guidance*" (Vol. 1 and Vol. 2) and is thereby acceptable for release for unrestricted use and the lease is ready for termination.



ATTACHMENT A

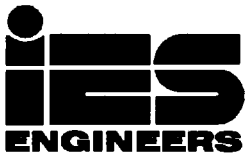
SURVEY MAPS AND WIPE RESULTS – PRIMARY AREAS (INCLUDES MAPS AND LSC PRINTOUTS)

PRELUDE RAM USE LAB DECOMMISSIONING SURVEY



PRELUDE RAM USE LAB DECOMMISSIONING SURVEY LOCATIONS

1. Blank
2. Floor Outside Door
3. Outside of Door
4. Inside of Door
5. Floor inside Door
6. Floor
7. Floor in Front of Sink
8. Sink Drain
9. Sink
10. Benchtop
11. Floor
12. Freezer Door
13. Floor in Front of Freezer
14. Bench Top (Work Area)
15. Bench Top (Work Area)
16. Bench Top (Work Area)
17. Floor in Front of Work Area
18. Waste Cabinet Door
19. Waste Cabinet Inside
20. Floor in front of Waste Cabinet
21. Work Area 2
22. Microbeta
23. Floor in front of Microbeta
24. Benchtop
25. Benchtop
26. Benchtop
27. Benchtop
28. Floor
29. Floor
30. Floor



ATTACHMENT B

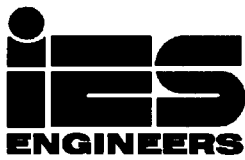
**SURVEY MAPS AND WIPE RESULTS – SECONDARY AREAS
(INCLUDES MAPS AND LSC PRINTOUTS)**

Prelude Decommissioning Secondary Survey Areas

Secondary Area Survey Locations



1. Blank
2. Door to the Outside
3. Floor inside door
4. Floor
5. Bathroom Door
6. Bathroom Door
7. Lab Door
8. Floor
9. Floor
10. Floor
11. Lab Door
12. Floor
13. Floor



ATTACHMENT C

**NRC FORM 314
CERTIFICATE OF DISPOSITION OF MATERIALS**



CERTIFICATE OF DISPOSITION OF MATERIALS

Estimated burden per response to comply with this mandatory collection request: 30 minutes. This submital is used by NRC as part of the basis for its determination that the facility is released for unrestricted use. Send comments regarding burden estimate to the FOIA, Privacy, and Information Collections Branch (T-6 F33), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by e-mail to InfoCollections.Resource@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOS-10202, (2150-0028), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

LICENSEE NAME AND ADDRESS

Prelude Therapeutics Incorporated
550 South College Avenue, Suite 100
Newark, DE 19713

LICENSE NUMBER

07-35398-01

DOCKET NUMBER**LICENSE EXPIRATION DATE**

February 28, 2027

A. LICENSE STATUS (Check the appropriate box)

- ☐ This license has expired. ☐ This license has not yet expired; please terminate it.

B. DISPOSAL OF RADIOACTIVE MATERIAL

(Check the appropriate boxes and complete as necessary. If additional space is needed, provide attachments)

The licensee, or any individual executing this certificate on behalf of the licensee, certifies that:

- ☐ 1. No radioactive materials have ever been procured or possessed by the licensee under this license.
- ☐ 2. All activities authorized by this license have ceased, and all radioactive materials procured and/or possessed by the licensee under this license number cited above have been disposed of in the following manner:
- ☐ a. Transfer of radioactive materials to the licensee listed below:
- ☐ b. Disposal of radioactive materials:
- ☐ 1. Directly by the licensee:
- ☐ 2. By licensed disposal site:
- ☐ 3. By waste contractor:
- ☒ c. All radioactive materials have been removed such that any remaining residual radioactivity is within the limits of 10 CFR Part 20, Subpart E, and is ALARA.

C. SURVEYS PERFORMED AND REPORTED

- ☒ 1. A radiation survey was conducted by the licensee. The survey confirms:
- ☒ a. the absence of licensed radioactive materials
- ☐ b. that any remaining residual radioactivity is within the limits of 10 CFR 20, Subpart E, and is ALARA.
- ☐ 2. A copy of the radiation survey results:
- ☒ a. is attached; or ☐ b. is not attached (Provide explanation); or ☐ c. was forwarded to NRC on: _____ Date _____
- ☐ 3. A radiation survey is not required as only sealed sources were ever possessed under this license, and
- ☐ a. The results of the latest leak test are attached; and/or ☐ b. No leaking sources have ever been identified.

The person to be contacted regarding the information provided on this form:

NAME	TITLE	TELEPHONE (Include Area Code)	E-MAIL ADDRESS
Min Wang, Ph.D.	Radiation Safety Officer	(302) 273-3366	mwang@preludetx.com

Mail all future correspondence regarding this license to:

Min Wang, Ph.D. - Radiation Safety Officer - Prelude Therapeutics Incorporated - Experimental Station
E400-3244, 200 Powder Mill Rd., Wilmington, DE, 19803

C. CERTIFYING OFFICIAL

I CERTIFY UNDER PENALTY OF PERJURY THAT THE FOREGOING IS TRUE AND CORRECT

PRINTED NAME AND TITLE	SIGNATURE	DATE
Krishna Vaddi, DVM, Ph.D., Founder		12/20/17

WARNING: FALSE STATEMENTS IN THIS CERTIFICATE MAY BE SUBJECT TO CIVIL AND/OR CRIMINAL PENALTIES. NRC REGULATIONS REQUIRE THAT SUBMISSIONS TO THE NRC BE COMPLETE AND ACCURATE IN ALL MATERIAL RESPECT. 18 U.S.C. SECTION 1001 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.



ACKNOWLEDGEMENT - RECEIPT OF CORRESPONDENCE

Name and Address of Applicant and/or Licensee

Kris Vaddi, DVM, Ph.D.
Chief Executive Officer and Founder
Prelude Therapeutics Incorporated
200 Power Mill Road
Experimental Station E400/3213
Wilmington, DE 19803

Date

December 13, 2017

License Number(s)

07-35398-01

Mail Control Number(s)

601936

Licensing and/or Technical Reviewer or Branch

Commercial, Industrial, R&D, and Academic Branch

This is to acknowledge receipt of your: ☒ Letter and/or ☐ Application Dated: December 1, 2017

The initial processing, which included an administrative review, has been performed.

☒ Amendment ☐ Termination ☐ New License ☐ Renewal☒ There were no administrative omissions identified during our initial review.☐ This is to acknowledge receipt of your application for renewal of the material(s) license identified above. Your application is deemed timely filed, and accordingly, the license will not expire until final action has been taken by this office.☐ Your application for a new NRC license did not include your taxpayer identification number. Please complete and submit NRC Form 531, Request for Taxpayer Identification Number, located at the following link: <http://www.nrc.gov/reading-rm/doc-collections/forms/nrc531.pdf>

Follow the instructions on the form for submission.

☐ The following administrative omissions have been identified:

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Your application has been assigned the above listed MAIL CONTROL NUMBER. When calling to inquire about this action, please refer to this control number. Your application has been forwarded to a technical reviewer. Please note that the technical review, which is normally completed within 180 days for a renewal application (90 days for all other requests), may identify additional omissions or require additional information. If you have any questions concerning the processing of your application, our contact information is listed below:

Region I
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Division of Nuclear Materials Safety
2100 Renaissance Boulevard, Suite 100
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(610) 337-5260, (610) 337-5313,
(610) 337-5398, (610) 337-5239