



August 3, 2026

Region III
U.S. Nuclear Regulatory Commission
DRSS/Materials Licensing Branch
2056 Westings Avenue, Suite 400
Naperville, IL 60563-2657

Re: POINT Biopharma USA Inc. – Radioactive Material License 13-35593-01 – Amendment

To whom it may concern:

POINT Biopharma USA Inc. (POINT) respectfully submits this Amendment to our Radioactive Materials License 13-35593-01 for your review. POINT requests expedited review as this authorization is intended to support a diagnostic to be used in an upcoming clinical trial, so a delay could affect the availability of that diagnostic for trial patients.

This request is to authorize possession of an additional isotope, as follows:

Byproduct, source, and/or special nuclear material	Chemical and/or physical form	Maximum amount that licensee may possess at any one time under this license	Authorized Use
Indium-111	Solid or Liquid	1 curie total	For research and development as defined in 10 CFR 30.4, including radioactive isotope labeling and calibration and checking of the licensee’s instruments. For manufacturing, preparation, processing, packaging, distribution, and redistribution of radiopharmaceuticals and/or radiochemicals for which the FDA has accepted an Investigational New Drug (IND) application, in accordance with the IND and with 10 CFR 32.72.



Thank you for consideration of our amendment to this license. Please contact me with any questions. We look forward to your response.

Sincerely,

Signed by:

A handwritten signature in black ink, appearing to read "Michael Abel", is shown within a rectangular box.



Signer Name: Michael Abel

Signing Reason: I am the author of this document

Signing Time: 03-Aug-26 | 13:20:12 EDT

138E28282D8F4C29909C6CBD7D3BA752

Michael Abel, PhD, CHP, DABR

Radiation Safety Officer

Director, Environmental Health & Radiation Safety

POINT Biopharma USA Inc. (a wholly owned subsidiary of Eli Lilly and Company)

Martha Pavon

From: Tammy Tomczak
Sent: Tuesday, August 4, 2026 7:53 AM
To: Martha Pavon
Cc: Sandy Pavon
Subject: FW: POINT Biopharma USA Inc. License No. 13-35593-01 Amendment Request
Attachments: Amendment_Request_-_License_No_13-35593-01_Cover_Letter_03Aug2026.pdf

Good morning, Martha 😊

Can you please add the attached to ADAMS?

Thank you!!
Tammy

From: Sara Forster <Sara.Forster@nrc.gov>
Sent: Monday, August 3, 2026 1:34 PM
To: Tammy Tomczak <Tammy.Tomczak@nrc.gov>; R3-DRSSMail Resource <R3-DRSSMail.Resource@nrc.gov>
Subject: FW: POINT Biopharma USA Inc. License No. 13-35593-01 Amendment Request

Hi, Tammy...

Could you please control this in and assign it to me? It is an expedite.

Thank you,

Sara

Sara Forster
U.S. NRC
630-829-9892
sara.forster@nrc.gov

From: Michael R Abel <michael.abel@lilly.com>
Sent: Monday, August 3, 2026 12:27 PM
To: R3DRSS.INTransfer <R3DRSS.INTransfer@nrc.gov>
Cc: Sara Forster <Sara.Forster@nrc.gov>
Subject: [External_Sender] POINT Biopharma USA Inc. License No. 13-35593-01 Amendment Request

Good afternoon,

Please find attached an amendment request to POINT Biopharma USA Inc. License No. 13-35593-01.

Please let me know if you have any questions.

Thank you, and kind regards,
Michael Abel

Michael Abel

Director, Environmental Health and Radiation Safety
463.271.0847 (office) | 574.527.0616 (mobile)
michael.abel@lilly.com



Eli Lilly and Company

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