UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE RD. SUITE 210
LISLE, IL 60532-4352

December 1, 2021

Todd Hockemeyer
Radiation Safety Officer
POINT Biopharma USA Inc.
4850 W. 78th St.
Indianapolis, IN 46268

SUBJECT: POINT BIOPHARMA USA INC. REQUEST FOR WRITTEN CONSENT TO DIRECT LICENSE TRANSFER AND AMENDMENT TO NRC LICENSE NO. 13-35593-01

Dear Mr. Hockemeyer:

Enclosed is Amendment No. 03 to your NRC Materials License No. 13-35593-01 in accordance with your request in letter dated May 20, 2021. In summary, you notified us of an upcoming business transaction that we subsequently determined constituted a change-of-control of this license. You provided additional information in letter date November 29, 2021, and, based on that and the aforementioned letter, we have amended your license documenting the circumstances related to the change-of-control.

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the U. S. Nuclear Regulatory Commission, Region III office at (630) 829-9887 so that we can provide appropriate corrections and answers.

By letter dated May 20, 2021 (Agencywide Documents Access and Management System (ADAMS) accession no. ML21160A110), POINT Biopharma USA Inc. submitted to the U.S. Nuclear Regulatory Commission (NRC) information that was determined to constitute a direct transfer of control of NRC Materials License No. 13-35593-01. Letter dated November 29, 2021 (ML21334A194) provided additional information on the matter so that written consent could be considered. In accordance with Section 184 of the Atomic Energy Act of 1954, as amended (AEA), and 10 CFR 30.34, the NRC consents to the transfer.

POINT Biopharma is authorized by the NRC for the possession and use of byproduct material under Part 30. Based on the information in the aforementioned letters, the NRC determined that POINT Biopharma needed written consent to the direct transfer of control of its license from the NRC. Because the license was issued under 10 CFR Part 30, “Rules of General Applicability to Domestic Licensing of Byproduct Material,” the NRC must find that the transfer is in accordance with the provisions of the AEA and, if so, must give its consent in writing prior to the transfer, in accordance with Section 184 of the AEA and 10 CFR 30.34(b). Additionally, the NRC staff reviewed the direct transfer of control request using the guidance in NUREG-1556, Volume 15, Rev. 1, “Consolidated Guidance About Materials Licenses – Guidance About

Changes of Control and About Bankruptcy Involving Byproduct, Source, or Special Nuclear Materials Licenses," dated June 2016.

10 CFR 30.34(b) states:

> (1) No license issued or granted pursuant to the regulations in Parts 30 through 36, and 39 nor any right under a license shall be transferred, assigned or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person, unless the Commission shall, after securing full information, find that the transfer is in accordance with the provisions of the Act and shall give its consent in writing.
>
> (2) An application for transfer of license must include:
>
> (i) The identity, technical and financial qualifications of the proposed transferee; and
> (ii) Financial assurance for decommissioning information required by 10 CFR 30.35.

As described in ADAMS accession nos. ML21160A110, dated May 20, 2021, and ML21334A194, dated November 29, 2021, the direct transfer of control resulted in POINT Biopharma transferring assets, including the location of use on the license, to a new parent company, POINT Biopharma Global, Inc. The direct transfer occurred on June 30, 2021. The details of the completed transaction were described in ADAMS accession nos. ML21160A110 and ML21334A194. The NRC staff finds that the licensee request adequately provides a complete and clear description of the transaction, consistent with 10 CFR 30.34(b) and Chapter 5 and Appendix E of NUREG-1556, Vol. 15, Rev. 1. The sufficiency of the description is evaluated below.

The request for a direct transfer of ownership was posted for public comment on the NRC website for 30 days in accordance with 10 CFR Part 2, Subpart M and as described in NRC's Regulatory Issue Summary 2014-08, Rev. 1. No comments were received from members of the public and was removed from posting on September 9, 2021.

The NRC conducted an inspection of POINT Biopharma at the licensee's location on August 19, 2021, and no violations were identified

Additionally, as described in its November 29, 2021 letter, POINT Biopharma commits that it:

A. will not change the radiation safety officer listed on the NRC license;

B. will not change personnel involved in licensed activities;

C. will not change the locations, facilities, and equipment authorized in the NRC license;

D. will not change the radiation safety program authorized in the NRC license; and

E. will maintain required surveillance records and decommissioning records as required by NRC regulations.

Based on these commitments, the NRC staff finds that the licensee request adequately documents the constraints, license conditions, requirements, representations, and commitments made by the transferee, consistent with 10 CFR 30.34(b) and Chapter 5 and Appendix E of NUREG-1556, Vol. 15, Rev. 1.

The NRC staff used the guidance provided by the NRC's Office of Nuclear Material Safety and Safeguards' "Checklist to provide a basis for confidence that radioactive materials will be used as specified on the application," January 29, 2019 revision. The purpose of this checklist is for the NRC to obtain reasonable assurance from new license applicants or NRC licensees transferring control of licensed activities that the licensed material will be used for its intended purpose and not for malevolent use. Therefore, for security purposes, POINT Biopharma Global Inc. is considered to be a known entity, having established itself as a publicly-traded company (NASDAQ) with the U.S. Securities and Exchange Commission (SEC).

An environmental assessment for this action is not required because this action is categorically excluded under 10 CFR 51.22(c)(21).

The staff has reviewed the request for a direct transfer of control of License No. 13-35593-01. The NRC staff finds that the direct transfer of control is in accordance with Section 184 of the AEA and 10 CFR 30.34(b) and consents to the transfer.

You will be periodically inspected by NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you. This could include issuance of a notice of violation, or imposition of a civil penalty, or an order suspending, modifying or revoking your license as specified in the General Statement of Policy and Procedure for NRC Enforcement Actions. Since serious consequences to employees and the public can result from failure to comply with NRC requirements, prompt and vigorous enforcement action will be taken when dealing with licensees who do not achieve the necessary meticulous attention to detail and the high standard of compliance which NRC expects of its licensees.

The NRC's Safety Culture Policy Statement became effective in June 2011. While a policy statement and not a regulation, it sets forth the agency's *expectations* for individuals and organizations to establish and maintain a positive safety culture. You can access the policy statement and supporting material that may benefit your organization on NRC's safety culture Web site at http://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html. We strongly encourage you to review this material and adapt it to your particular needs in order to develop and maintain a positive safety culture as you engage in NRC-regulated activities.

In accordance with 10 CFR 2.390, a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records component of NRC's Agencywide Documents Access and Management System (ADAMS). ADAMS is accessible from the NRC website at https://www.nrc.gov/reading-rm/adams.html. If you have any questions regarding this letter, please contact Bryan Parker at 678-828-7050 or via electronic mail at bryan.parker@nrc.gov.

Sincerely,

Bryan A. Parker

Digitally signed by Bryan A. Parker
Date: 2021.12.01 14:07:19 -05'00'

Bryan A. Parker
Senior Health Physicist
Materials Licensing Branch

License No. 13-35593-01
Docket No. 030-39229

Enclosure: Amendment No. 03