



Our STN: BL 125678

Bavarian Nordic A/S
Attention: Todd Phillips
1005 Slater Road
Suite 101
Durham, NC 27703

May 28, 2024

Dear Dr. Phillips:

We have completed our review of the data to support an extension of expiration of Jynneos lot #96867 under 564A(b). This letter is to notify you that in accordance with 564A(b) of the FD&C Act, we are extending the expiration and authorizing the introduction or delivery for introduction into interstate commerce after the expiration provided by the manufacturer, for the following lot of Jynneos:

- Lot #96867

Storage shall be at -20°C for up to 3 years and the vaccine may be thawed and kept at +2°C to +8°C (+36°F to +46°F) for 8 weeks within the expiry.

If you have any questions, please contact the Regulatory Project Manager, Josephine Resnick at (301-796-2640) or by email at Josephine.Resnick@fda.hhs.gov.

Sincerely,

/s/

Jerry P. Weir
Director
Division of Viral Products
Office of Vaccine Research and Review
Center for Biologics Evaluation and Research