



Our STN: BL125678/133

SUPPLEMENT APPROVAL

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

October 18, 2024

Dear Dr. Phillips:

We have approved your request received September 25, 2024, to supplement your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act for Smallpox and Monkeypox Vaccine, Live, Non-replicating (JYNNEOS), manufactured at your Kvistgaard, Denmark, and Grand Rapids, MI, facilities, to extend the expiration for final drug product lots FDP00017, FDP00018, FDP00019 and FDP00020 to August 31, 2026.

We will include the information contained in the above-referenced supplement in your BLA file.

Sincerely,

Jerry P. Weir, Ph.D.
Director
Division of Viral Products
Office of Vaccines Research and Review
Center for Biologics Evaluation and Research