Our STN: BL 125678/65 **SUPPLEMENT APPROVAL**

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

September 29, 2023

Dear Dr. Phillips:

We have approved your request received March 31, 2023, 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 revise the JYNNEOS Package Insert (PI) as follows:

- To include syncope in Section 5 (*Warnings and Precautions*).

- To add Section 6.2 (*Postmarketing Experience*) to the PI to include the following adverse reactions:
  - Cardiac Disorders: myocarditis, pericarditis
  - Immune System Disorders: hypersensitivity reactions, including angioedema, rash, and urticaria
  - Nervous System Disorders: dizziness, syncope
  - General disorders and administration site conditions: injection site warmth, injection site vesicles.

LABELING

We hereby approve the draft content of labeling: Package Insert submitted under amendment #2 dated June 28, 2023.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the final content of labeling (21 CFR 601.14) in Structured Product Labeling (SPL) format via the FDA automated drug registration and listing system, (eLIST) as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the Package Insert submitted on June 28, 2023. Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As* at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

All final labeling should be submitted as Product Correspondence to this BLA, STN BL 125678 at the time of use and include implementation information on Form FDA 356h.

ADVERTISING AND PROMOTIONAL LABELING

You may submit two draft copies of the proposed introductory advertising and promotional labeling with Form FDA 2253 to the Advertising and Promotional Labeling Branch at the following address:

Food and Drug Administration
Center for Biologics Evaluation and Research
Document Control Center
10903 New Hampshire Ave.
WO71–G112
Silver Spring, MD 20993-0002

You must submit copies of your final advertising and promotional labeling at the time of initial dissemination or publication, accompanied by Form FDA 2253 (21 CFR 601.12(f)(4)).

All promotional claims must be consistent with and not contrary to approved labeling. You should not make a comparative promotional claim or claim of superiority over other products unless you have substantial evidence or substantial clinical experience to support such claims (21 CFR 202.1(e)(6)).

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

Sincerely,

David C. Kaslow, MD
For Acting Deputy Director - Clinical
Division of Vaccines and
Related Products Applications
Office of Vaccines
Research and Review
Center for Biologics
Evaluation and Research