



Our STN: BL 125678/119

## **SUPPLEMENT APPROVAL**

March 31, 2025

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

Dear Dr. Phillips:

We have approved your request received May 31, 2024, to supplement your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act for Smallpox and Mpox Vaccine, Live, Non-replicating (JYNNEOS), manufactured at your Bavarian Nordic A/S, Kvistgaard, Denmark facility, to include a two-vial presentation of JYNNEOS that consists of a Lyophilized Antigen Component vial and a Diluent Component vial.

The review of this supplement was associated with the following National Clinical Trial (NCT) numbers: NCT 03699124; NCT 01668537.

### **LABELING**

We hereby approve the draft content of labeling: Package Insert submitted under amendment 28 dated March 27, 2025, and the draft carton and container labels submitted under amendment 20 dated March 12, 2025.

### **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 March 27, 2025. 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.

## **CARTON AND CONTAINER LABELS**

Please electronically submit final printed carton and container labels identical to the carton and container labels submitted on March 12, 2025, according to the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications* at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-regulatory-submissions-electronic-format-certain-human-pharmaceutical-product-applications>.

All final labeling should be submitted as Product Correspondence to this BLA, STN BL 125678/119 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)).

For each pending supplemental application for this BLA that includes proposed revised labeling, please submit an amendment to update the proposed revised labeling with the changes approved today.

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

Sincerely,

R. Douglas Pratt, MD, MPH  
Deputy Director  
Division of Clinical and Toxicology Review  
Office of Vaccines Research and Review  
Center for Biologics Evaluation and Research