Our STN: BL 125678/51

SUPPLEMENT APPROVAL
March 16, 2023

Bavarian Nordic A/S
Attention: Laura Kron
Bavarian Nordic Inc.
1005 Slater Road, Suite 101
Durham, NC 27703

Dear Ms. Kron:

We have approved your request received November 14, 2022, 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) to provide for the addition of Grand River Aseptic Manufacturing (GRAM) facilities located in Grand Rapids, Michigan for drug product formulation and filling, and GRAM at Caledonia, Michigan as a new finishing site for Liquid Frozen MVA-BN Drug Product (DP) manufacture as well as addition of (b) (4) in (b) (4) for DP sterility release testing.

Also, we are approving your comparability protocol to provide for the addition of GRAM Filling Line (b) (4).

We acknowledge your statement in your March 15, 2023, submission that the agreed upon Dear Health Care Provider (DHCP) letter explaining an error in the shelf-life of JYNNEOS stored at 2-8°C after thawing from -20°C will be included in shipments of JYNNEOS which bear this labeling error.

COMPARABILITY PROTOCOL

Under 21 CFR 601.12(e), approval of a comparability protocol may justify a reduced reporting category for a particular change. You should report information confirming that the change meets the requirements specified in your approved comparability protocol as a **Supplement – Changes Being Effected in 30 Days** (21 CFR 601.12(c)). You should include the information described in 21 CFR 601.12 (b)(3) in this supplement. Although you may distribute the product made using this change 30 days after FDA receives the supplement, continued use of the change will be subject to our final approval of the supplement.

LABELING

We hereby approve the draft content of labeling Package Insert submitted under amendment #8, dated March 15, 2023, and the draft carton and container labels submitted under amendment #1, dated December 7, 2022.

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 15, 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.

CARTON AND CONTAINER LABELS

Please electronically submit final printed carton and container labels identical to the carton and container labels submitted on December 7, 2022 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 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)).

Please submit an amendment to all pending supplemental applications for this BLA that include revised labeling incorporating a revised content of labeling that includes these changes.

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

Sincerely,

Carolyn Renshaw
Director
Division of Manufacturing and Product Quality
Office of Compliance and Biologics Quality
Center for Biologics Evaluation and Research