Our STN: BL 125678/20 **SUPPLEMENT APPROVAL**

Bavarian Nordic Inc.
Attention: Maria Oyaski June 16, 2021
3025 Carrington Mill Blvd.
Suite 100
Morrisville, NC 27560

Dear Ms. Oyaski:

We have approved your request submitted and received on December 17, 2020, to supplement your Biologics License Application (BLA) under section 351(a) of the Public Health Service Act for Smallpox and Monkeypox Vaccine, Live, Non-replicating (JYNNEOS), manufactured at the Bavarian Nordic A/S, Kvistgaard, Denmark, (b) (4) (b) (4) facilities, to revise the labeling to include the residual amount of ciprofloxacin (≤ 0.005 mcg/ 0.5 mL dose) in the JYNNEOS drug product resulting from the addition of ciprofloxacin to the drug substance manufacturing process (approved under STN 125678/13).

LABELING

We hereby approve the draft content of labeling: Package Insert submitted under amendment #3, dated June 16, 2021, and the draft carton and container labels submitted December 17, 2020, and under amendment #1, dated February 16, 2021, respectively.

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 16, 2021. 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 17, 2020, and February 16, 2021, 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)).

We will include 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