Our STN: BL 125820/63

SUPPLEMENT APPROVAL
April 22, 2026

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

Dear Dr. Phillips:

We have approved your request received December 22, 2025, to supplement your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act for Chikungunya Vaccine, Recombinant (VIMKUNYA), to include the optimization of the drug substance (DS) and bulk drug product (BDP) manufacturing processes for the chikungunya virus-like particle (CHIKV VLP) drug product (DP), at your (b) (4) facility, and the associated labeling changes.

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 9, dated April 17, 2026.

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 April 17, 2026. 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 125820, 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,

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